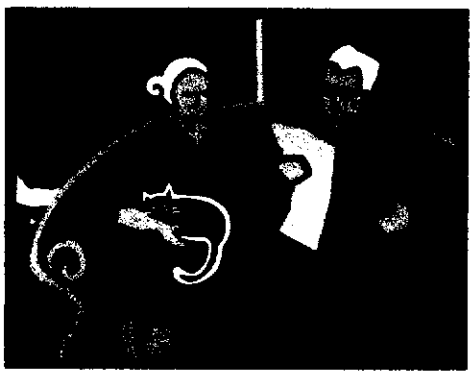
JAN 28 2005

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Part 423
[CMS-0011-P]
RIN 0938-AN49
Medicare Program; E-Prescribing and the Prescription Drug Program
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Proposed rule.
SUMMARY: This rule proposes to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in our incremental approach to adopting final uniform standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.
DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later



1/27/05

than 5:00 p.m. on [OFR--insert 60 days after the date of publication in the Federal Register].
ADDRESSES: In commenting, please refer to file code CMS-0011-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):
1. Electronically. You may submit electronic comments to http://www.cms.hhs.gov/regulations/ecomments (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).
2. By mail. You may mail written comments (one original and two copies) to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P,
P.O. Box 8014,
Baltimore, MD 21244-8014.

Dear1/27/2005 3:57:14 PM Secretary

How do you propose to have us use the internet and how do you propose to electronic comment if we do **NOT** understand the format. Why is getting drugs getting Harder? First of all, the eyes don't cooperate after 60, then there is the problem with the fingers. I am having a hard time with this. Hard because I have psorasis on my hands. With Psoratic Arthritis in the knuckles and joints.This is documented. I have SSI for this reason.
Can You send me a copy of this information so I may participate in the discussion. Or perhaps that is not a good idea. Who WantS to listen anyway?
So Please, Lets not make things harder to save a buck. A $ is a $
Sincerely Shirley Miles 20 County Fair Trail St. Peters MO 63376

Shirley Miles

Response

Thank you for your feedback. It has been fowarded to the appropriate parties.
Discussion Thread

Customer - 01/27/2005 04:43 PM
This feedback is about:
http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=1.

Adobe and Long Term Care information should be part of the MainFrame of CMS and HIPAA explaining in Language we seniors understand.
Thank You for making it simpler.

I have appealed a ruling of United Health Cares Medicare Complete coverage with the insurance company in referencing the cost of perscriptions in ENBREL.....

I'm between a rock and a hard place trying to understand the terms.
Thanks
Sirley Miles
20 County Fair Trail
St. Peters MO
p.s. Our new Governor Blutt is cutting many state run programs. Therefore I need to understand better the Availabity of Government Programs under SSI and What drugs are allowed to Disabled.

Question Reference #050127-000011

Category: Appeals Policy
Contact Information: shirleymiles@charter.net
Date Created: 01/27/2005 04:43 PM
Last Updated: 01/27/2005 04:43 PM
Status: Solved
State:

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Minneapolis, MN 55404-3840
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Mailing Address:
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Minneapolis, MN 55440-1469

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March 17, 2005

MAR 23 2005

ALLINA
Hospitals & Clinics

Mark McClellan, MD, PhD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
Post Office Box 8014
Baltimore, MD 21244-1850

Re: Medicare Program: E-Prescribing and the Prescription Drug Program; Proposed Rule (Vol. 70 No.23 Federal Register, February 4, 2005)

Dear Dr. McClellan:

On behalf of Allina Hospitals and Clinics, I appreciate the opportunity to comment on the proposed rule concerning proposed standards for an electronic prescription drug program. Allina Hospitals & Clinics is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, to medical transportation, pharmacy and hospice services. Allina serves communities around Minnesota and in western Wisconsin. We are in the process of implementing the electronic medical record across all of our hospitals and clinics and have a vested interest in this rule as we consider the future application of electronic prescribing.

We appreciate the step by step approach that CMS is taking in regard to e-prescribing and see pilot testing of all standards as a key requirement before any standards are to be implemented. Please do not move forward with implementation requirements until all of the kinks have been worked through via pilot testing.

We have two main areas of concern with the proposed rule, the use of the NPI and the 270/271 eligibility standards.

I. BACKGROUND

We support the use of the National Provider Identifier (NPI) as the provider identifier in the electronic prescribing program, however we feel very strongly that the NPI should not be mandated for use until the national deadline is in place for current HIPAA transactions. Large provider groups, like Allina, are waiting for CMS to develop a method to bulk-enumerate our thousands of physicians. CMS has told us it would not even have an idea of how bulk enumeration will work until late 2005. We had been told that this would occur by September but just last Monday on a national WEDI SNIP NPI call, a CMS representative indicated that we wouldn't know anything more until year end. Without the ability to bulk enumerate until late 2005, there is no possibility that large provider groups would be ready to use the Identifiers by January 2006. This is a significant issue since the most likely groups to use e-prescribing are the large provider groups.

II. PROVISIONS

The proposed 270/271 eligibility standard is a mandated HIPAA standard but is not yet widely used. Initial implementations have shown that there is much room for improvement on what data should be in the 271 responses. The industry must come to agreement on terms and definitions. We do not support the use of this standard until NCPDP is able to complete the guidance document and pilot testing of the standard has documented success.

Thank you for the opportunity to respond to these proposed standards. We look forward to the next stage in the development of a solid foundation for electronic transactions. Please feel free to contact me if you have any questions regarding our comments. I can be reached at 612-775-9744.

Sincerely,

Nancy G Payne

Nancy G. Payne, RN, MA
Director Regulatory Affairs

medco

Gary Levine
Senior Director
Business Planning & Development

Medco Health Solutions, Inc.
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April 4, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Madams/Sirs:

Medco Health Solutions, the nation's largest pharmacy benefit manager appreciates the opportunity to submit comments in response to the Department of Health and Human Services' Center for Medicare and Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) on February 4, 2005. The proposed rule, at 70 *Fed. Reg.* 6256-6274, is intended to be based on section 1860D-4(3) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).

In our comment letter we wish to make the following major points with respect to preemption of state laws and regulations that conflict with e-prescribing and the MMA:

BACKGROUND

"A2. Statutory Basis: State Preemption"

1. The Scope of Preemption in the Final Rule Should be Broadened so that the Standards Issued Under the Rule Facilitate Rather than Impede Nationwide e-Prescribing

The narrow scope of the preemption language proposed in the NPRM would make e-prescribing more difficult once a final rule is adopted. In its current form, the proposed rule seems to simply add one more narrow set of rules for e-prescribing standards on top of the confusing web of state legal restrictions. The current – and proposed – landscape greatly impedes the development of a nationwide e-prescribing standard.

Medco firmly believes that the standards of the final rule should be written to preempt any state law that is contrary to the standards or restricts the ability to carry out the MMA. Further, the final rule should be written so that federal preemption pertains to the electronic transmission of any information relating to medication history, eligibility, benefits, and prescriptions with respect to covered Part D drugs. Only then can the regulations facilitate the progress of e-prescribing within the timeframe envisioned in the MMA.

The NPRM itself recognizes that e-prescribing will bring many benefits to the American healthcare system. The U.S. healthcare delivery system currently is complex, inefficient, and highly fragmented. The Institute of Medicine concluded that the application of health information technology can improve both the efficiency and the quality of healthcare costs.[1]

The application of such technology to prescriptions is an especially important source of potential improvements. Patient health will benefit from a reduction in medication errors and adverse drug events, which, according to the Institute of Medicine, account for more than 770,000 injuries or deaths each year in hospitals. E-prescribing can reduce the incidence of medication errors by, among other things, helping to prevent illegible scripts and by providing prescriber access at the point of care information about potentially dangerous drug interactions. One study cited by the Institute for Safe Medication Practices (ISMP) found a 55% reduction in medication errors after electronic prescribing was instituted.[2]

E-prescribing also can help providers monitor whether the patient actually receives the prescribed medicine. According to one estimate, about one-third of written prescriptions may not be filled nor delivered to patients. Noncompliance with medication regimens is associated with over 125,000 deaths annually in the United States.[3] Finally, e-prescribing can reduce the burdens and costs on physicians. The NPRM cites estimates that almost 30 percent of prescriptions require pharmacy callbacks that result in 900 million prescription-related telephone calls placed annually. (NRPM, p. 6260). Electronic interactions through e-prescribing can greatly reduce the number and extent of such interruptions for prescribers. As the NRPM concludes (p. 6260), "...even small improvements in quality that are attributed to e-prescribing may translate into significant health benefits."

Due to these acknowledged benefits, the MMA has created a comprehensive electronic prescription program for payors, providers and pharmacies that manage benefits and prescribe and dispense covered Part D drugs. Congress did not expressly require the adoption of e-prescribing by Prescription Drug Plans (PDPs), Medicare Advantage plans that offer a pharmacy benefit program (MA-PDs) or providers, but provided that HHS would promulgate uniform standards for those that do adopt the e-prescribing program. However, in the NRPM HHS has mandated that PDPs and MA-PDs shall implement electronic prescribing programs and that the programs utilizing the foundation standards should be available on January 1, 2006. While participation by providers and pharmacies is voluntary, some will utilize e-prescribing because of contractual requirements of a health benefit plan in which they participate.

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[1] Institute of Medicine, To Err Is Human: Building a Safer Health System (Washington, DC: November 1999) and Crossing the Quality Chasm: A New Health System for the 21st Century (Washington, D.C.: March 2001).

[2] Institute for Safe Medication Practices (ISMP), white paper, "A Call to Action: Eliminate Handwritten Prescriptions Within 3 Years!" 2000.

[3] National Association of Chain Drug Stores (NACDS), "The Chain Pharmacy Industry Profile 2001."

The MMA requires that e-prescribing include real-time electronic delivery of certain specific information on eligibility, benefits, drug interactions, warnings, dosage adjustments, medication history, and the availability of generic substitutes to providers and pharmacists. This information must be provided in a secure format that complies with health privacy regulations. The system also must permit the electronic exchange of FDA drug labeling and listing information. E-prescribing systems are intended to provide a near-term foundation for the continuing implementation of systems for electronic medical records.

The MMA contains a statutory requirement for HHS to issue regulations that provide standards for e-prescribing that pertain to electronic prescribing programs. It sets an ambitious schedule for issuance of the e-prescribing standards and their implementation.

Three factors are critical to the development of a nationwide e-prescription capability. First, participation – especially by physicians – is voluntary. Moreover, the adoption of e-prescribing systems involves externalities; the benefits also accrue to other parties besides the physician or pharmacy that adopts the system. This means that the parties who benefit from e-prescribing must have flexibility to compensate one another and create incentives for prescribers and pharmacies to adopt new e-prescribing systems. The MMA recognizes this and authorizes the Secretary of HHS to provide incentive payments to physicians to help defray their costs. As discussed below, the MMA also provides for a safe harbor from federal anti-kickback laws and an exemption from federal limitations on physician referrals (the "Stark law") so that participants in the e-prescribing network can compensate one another for joining.

The second critical factor in e-prescribing is scale. In other words, similar to the expansion of the telephone or Internet, the e-prescribing system will offer increasing benefits that multiply according to the number of participants in the system. To achieve scale requires that as many appropriate parties as possible – physicians, pharmacies, hospitals, pharmacy plans, pharmacy benefit managers, etc. – be included in the expanding network. Scale also requires a nationwide system that is accessible by parties who are located in all parts of the country. Again, the MMA recognizes this and requires HHS to issue regulations to create national uniform standards that preempt any state law or regulation. This preemption would include information that pertains to the electronic transmission of a medication history, information on eligibility, benefits, and prescriptions for covered Part D drugs and that is contrary to federal standards or restricts the ability to carry out the electronic prescribing program for Part D medications.

Tthe MMA does not require HHS to issue regulations defining the scope of that preemption. Rather, the standards themselves automatically preempt conflicting or burdensome state laws and regulations. The purpose of any HHS action to define the scope of preemption in regulations should be to make the process of implementing the standards as smooth as possible to facilitate and encourage their adoption so that HHS can meet the tight deadlines for e-prescribing that the MMA sets.

The third necessary element in e-prescribing is interoperability. The history of electronic technology development is littered with multiple systems that could not talk to one another. Today, even companies that produce potentially proprietary information technology systems recognize the benefits of interoperability.[4] This relates to scale. With interoperability, the participants in an information network reap substantially greater benefits than if that network is divided into smaller fiefdoms.

The MMA addresses the issue of interoperability in multiple ways.[5] To institute nationwide e-prescribing, the MMA requires the Secretary of HHS, with recommendations of the National Center for Vital Health Statistics (NCVHS), based on consultations with a range of industry and government stakeholders, to adopt, recognize, or modify uniform standards for the e-prescribing program. The Secretary must develop initial standards by September 1, 2005 and must pilot test them beginning in 2006 unless the Secretary determines that the initial standards reflect "adequate industry experience." Final standards must be in place by April 1, 2009.

To assure interoperability, and preclude the division of the country into separate areas that might lack access to the common e-prescribing network, the MMA provides that the standards will preempt state laws and regulations that conflict or interfere with e-prescribing programs. Without preemption, as will be discussed below, e-prescribing would lack both the scale and interoperability that are needed for a successful nationwide system.

2. E-Prescribing Can Become a Practical Reality Within the Timeframe Mandated by the MMA Only if HHS Issues Standards That Effectively Preempt Conflicting State Laws

There is a consistent and growing body of knowledge about the factors that, until now, have impeded the emergence of e-prescribing on a nationwide basis. One major factor is the reluctance of physicians to adopt new e-prescribing technologies.[6] The other factor is

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[4] See, e.g., Steve Lohr, "High-Tech Alliance on Base for a Digital Health Network," *New York Times*, January 26, 2005. ("Eight of the nation's largest technology companies, including IBM, Microsoft and Oracle, have agreed to embrace open, nonproprietary technology standards as the software building blocks for a national health information network.")

[5] In addition to creating the Electronic Prescription Drug Program, the MMA provides for a number of initiatives that relate to electronic or technology-enabled programs to reduce costs and improve quality of care. These initiatives include: a) grants to physicians to implement electronic prescription drug programs (Section 101); b) an IOM Study on Safety and Quality to provide a blueprint for system-wide change (Section 107); c) an IOM Study on Performance Measures to identify information technology requirements in aligning performance to payment for service (Section 238); d) an extension of telemedicine demonstrations and doubling the available authorized funding for patient safety improvements using information technology (Section 417), e); a 3 year CMS pay-for-performance demonstration program using health care information technology at 4 separate sites (Section 649); f) establishment of a new Council for Technology and Innovation within CMS for oversight of technology enhancements (Section 942), g) establishment of a new Commission on Systemic Interoperability to focus on standards development acceleration and adoption (Section 1012); and h) creation of a health care infrastructure loan program including $200 million in grant funding over 54 months for loans to providers to implement technology (Section 1016).

[6] "In health care, the average investment in information technology computer hardware, software, and services is only about $ 3,000 annually for each worker, compared with $ 7,000 a worker on average for private industry and nearly $ 15,000 a worker in banking....But health care remains a fragmented industry, with much of the care still

the patchwork of overlapping and sometimes conflicting state laws, and regulations issued pursuant to those laws, that make e-prescribing difficult if not impossible.

The e-prescribing regulations that HHS will issue to implement the MMA have the potential to help resolve both of these interrelated issues. The NRPM, however, takes a cautious approach that should be modified in the final regulations if they are to help rather than hinder the expansion of an e-prescribing network.

One way to overcome physician inertia is to provide incentives for them to adopt the new electronic technologies needed for e-prescribing. This is a mandate on HHS as a part of President Bush's Executive Order on Incentives for the Use of Health Information Technology, E.O. 13335, issued April 27, 2004.

While plans or pharmacy benefit managers may have an opportunity to lower a physician's capital requirements to provide adopt electronic prescribing capabilities through incentives, as the NPRM also points out, a major impediment to the provision of these needed incentives is the existence of federal and state laws prohibiting kickbacks and physician self-referrals. The NPRM states that HHS will address these impediments by issuing a proposed rule to create an exception under Section 1877 of the Act (the "Stark law") for incentives relating to e-prescribing and that the department's Inspector General is considering how best to establish a safe harbor under the federal Anti-Kickback statute.

The Government Accountability Office points out that state law is prevalent in this field: "Many states have laws analogous to the federal self-referral and anti-kickback laws, some of which are stricter or have fewer exceptions, or both."[7] However, the proposed rule fails to preempt or otherwise address these conflicting and burdensome state laws.

The second major impediment to the spread of e-prescribing is the patchwork of laws and regulations in the 50 states and the District of Columbia. Section 1860D-4(e) of the MMA addresses this impediment in clear language. It directs HHS to issue standards that preempt any state law that pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs and that is contrary to the standards or restricts the ability to carry out the MMA.

However, the NPRM does not adopt the statutory requirement. It would limit (p. 6257) any preemption to prescriptions with respect to covered Part D drugs *prescribed for Part D eligible individuals*. This approach unreasonably narrows the scope of the MMA with respect to e-prescribing. E-prescription depends on the ability of prescribers and other members of e-prescription networks to conform their e-prescribing systems to a single set

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provided by physicians in small practices." Steve Lohr, "Health Industry Under Pressure to Computerize," *New York Times*, February 19, 2005.

[7] Government Accountability Office, *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, GAO-04-991R, August 13, 2004, p. 47.

of standards that apply across the nation. The public is not well served by policies that permit conflicting state laws and regulations to preclude a nationwide e-prescribing system.

Virtually all payors' and providers' patient bases have multiple and different benefit programs. Applying standards only to Part D beneficiaries for covered Part D drugs creates multiple problems. In states that prohibit e-prescribing, for example, a prescriber would need to create a system exclusively for prescriptions for Part D individuals, while continuing to prescribe by hand for all other prescriptions for those states.[8] Also, in cases where Part D coverage might be denied for a patient at a time after the physician has written a prescription for an eligible Part D drug, the physician then would face the prospect of being found in violation of a state law that otherwise would have been preempted. The Pharmacy that dispensed the prescription would also find itself at risk. Expanding preemption to Part D patients rather than covered Part D drugs makes more sense.

Besides states that prohibit e-prescribing outright, the major problem that exists involves the myriad of often small differences between state laws or regulations that can prevent e-prescribing from achieving the needed scale and degree of coverage to be attractive to many prescribers. While any one standard may be beneficial, a multiplicity of requirements makes uniform coverage difficult if not unworkable. Consider the following state requirements presented in testimony of the National Association of Boards of Pharmacy (NABP) to the NCVHS Subcommittee on Standards and Security[9]:

- The states of Nevada and Ohio require that the state Board of Pharmacy approve the e-prescribing system (NABP, pp. 7 and 9).
- The state of Washington requires such Board approval every three years (NABP, p. 11).
- In Maryland, any "commercial intermediary must guarantee the confidentiality and security of transmission process in a manner approved by the Board" (NABP, p. 5).
- The states have varying requirements for prescription forms. For example, the state of Alabama allows electronic transmission but requires that the prescriber must write "Brand Medically Necessary" whenever a specific brand must be dispensed (NAPB, p. 1).
- The states have a variety of requirements concerning whether a prescriber may provide the electronic prescription to a pharmacy through an intermediary and the nature of permitted intermediaries.
- The states have a variety of electronic signature requirements.

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[8] The testimony of the National Association of Boards of Pharmacy to the NCVHS Subcommittee on Standards and Security, July 28, 2004, identifies South Carolina and South Dakota as states that do not allow electronic transmission of prescriptions. See p. 10.

[9] *Ibid.* at the pages indicated.

Such requirements are serious obstacles to the expansion of e-prescribing. For example, the requirement for Board approval of the system creates the risk that the Board of Pharmacy of a single state might invalidate a system in which the e-prescriber has made a significant investment. It also risks freezing the level of technology in cases where a Board publishes an approved list of e-prescribing systems that is only infrequently updated.

Depending on the state, some of the conflicting requirements are set by law while others appear in regulations. Indeed, state regulations can be more troublesome than state statutes because (1) they can often be proposed and adopted with little public notice (as compared to state statutes) and (2) they can be difficult for a party to obtain, compared to statutes that the states often codify.

Whether embodied in state laws or regulations, state requirements vary in ways that impede the development and implementation of nationwide standards. For example, electronic signature requirements differ among the states, as do requirements about whether the physician may transmit the prescription to the pharmacy through an intermediary. A major potential impediment for prescribers is the variation in prescription forms of each state; to assure interoperability, prescribers need to have access to a standard prescription form that applies regardless of the state where a patient may decide to obtain his or her prescription medication. This is needed, for example, to accommodate the needs of elderly patients who may move from their homes to warmer climates in the winter.

The specific and varying state requirements come on top of other state laws and regulations, such as the anti-kickback and physician self-referral laws noted above, that do not expressly reference e-prescribing despite posing significant obstacles to the implementation of nationwide electronic provision of prescription services. .

The problem with variable and changing state requirements is that prescribers face significant sanctions if they fail to comply with each of them. This creates enough uncertainty that prescribers are unlikely to actively implement an e-prescribing system even if they were able to achieve technical compliance with each state's requirement at a particular time. At a minimum, there are significant incentives for providers of electronic delivery of prescription drug services to skip service to states where the requirements are onerous, unclear, or at variance with requirements of a number of other states. The Government Accountability Office observes:

> "[H]ealth care providers are uncertain about what would constitute violations of those laws or create a risk of litigation. To the extent that there are uncertainties and ambiguity in predicting legal consequences, health care providers are reluctant to take action and make significant investments in health IT."[10]

[10] *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, p. 44.

The MMA sets an ambitious timetable for the enactment by HHS of the standards needed to make nationwide e-prescribing a reality. If HHS is to meet this timetable, then the rules that promulgate the needed framework for e-prescribing standards, including the final rule for the standards in the current rulemaking, should adopt a more complete reading of the MMA's statutory mandate to preempt state laws.

3. Congress Expressly Preempted the Field of Electronic Prescribing

To properly assess the intent of Congress, not only the language of the statute but also the full scope of the MMA and the Part D benefit must be considered. First, Congress recognized that electronic prescribing was an important step in establishing an electronic infrastructure for the U.S. health care system. It is clear that Congress mandated these broader initiatives in recognition of the multiple barriers to the objective of creating such an infrastructure and not just in implementing e-prescribing programs. See footnote 5, *supra*.

Second, Congress defined the Part D benefit to include far more than the cost of the drugs. As a component of the Part D benefit, beneficiaries are entitled to the following: (1) access to drug specific information on covered Part D drugs, including through pharmacy networks, how a PDP formulary functions and how a beneficiary can obtain access to information about access to Part D covered drugs and pharmacy networks, formularies and beneficiary cost-sharing requirements, (2) mechanisms for responding to beneficiary questions and providing information via the Internet about changes to formularies and explanations of benefits, (3) access to pharmacies, (4) meeting requirements for development of formularies that must include products in every therapeutic category and periodic evaluations of treatment protocols and procedures, and (5) cost and utilization management, quality assurance and medication therapy management programs. The medication therapy management programs are targeted to beneficiaries with multiple conditions, taking multiple drugs and likely to exceed drug spending targets set by HHS. The elements of the program include patient compliance regimens, (refill reminders, special packaging and other programs and means), and coordination with chronic care improvement programs. By definition, the full scope of the Part D benefit goes far beyond the acts of paying for Part D drugs and includes a broad set of entities and transactions. The preemption provisions provide in § 1860D-4(e)(5):

> The standards promulgated under this subsection shall supersede any State law or regulation that--(A) is contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

The meaning of the term "standards' is important. As set forth above, Congress meant that a comprehensive drug benefit and attendant health care components would be greatly enhanced by an electronic prescribing program. As such, the statutory definition and scope of the term "standards" is very broad.

"E. Current E-Prescribing Environment"

Standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. We recommend that the final standards be flexible and scalable in an effort to encourage adoption from small to large health care organizations and low to high-volume prescribing physician specialties. Electronic prescribing standards must allow for basic stand alone electronic prescribing platforms that permit small practices to meet the regulatory requirements without an undue financial burden. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency, and integration with existing management software and electronic medical record systems when making an investment.

Medco recommends that HHS encourage DEA to publish its long awaited decision on electronic signatures, and that it be applicable to more than just highly controlled substances such that prescribers and dispensers do not have to implement multiple electronic prescribing requirements, but rather a single effective and practical method which will encourage the full benefits of e-prescribing.

"F. Evolution and Implementation of an Electronic Prescription Drug Program"

Process for evolution of standards:

Medco believes that a private sector approach through ANSI accredited SDOs for standards development for e-prescribing is needed, with the federal government participating in the standards development process. We recommend that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to what has been experienced with the HIPAA administrative transactions standards

In addition, Medco recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards have an open updating process and any interested party should be eligible to submit proposals for additions and modifications to the standards. In addition, we suggest a responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders maintain the vocabularies. Medco does not believe that it necessary for all the vocabulary developers to be ANSI accredited, however the organization maintaining the code sets should ensure continuity and efficient updating of the standard over time.

"G. Electronic Prescription Drug Program"

Versioning of standards

Medco recommends that:

- HHS adopt minimal version levels of the standards;
- HHS depend on existing SDO enhancement processes for newer versions;
- Health care organizations be permitted to use newer versions provided there is backward compatibility. Medco recommends NCVHS periodically conduct hearings to determine when new minimum version levels should be adopted. If NCVHS considers the proposed changes to be substantive (as described in Federal Register Page 6267) HHS would issue a NPRM within 90 days. If the change is not substantive, it would waive notice and comment.

Medco is concerned about any possible divergence between HIPAA standard transactions and the same transactions, such as the 270/271 eligibility inquiry, that are employed in this NPRM. Therefore, we recommend that procedures be designed to meet the changing needs of HIPAA and e-Prescribing, but that such modifications to standards do not result in multiple standards.

Use of National Provider Identifier

Medco believes standard identifiers are extremely important for these transactions. It makes the following recommendations:

- That the NPI be the primary identifier for prescribers and dispensers.

- That current identifiers not be required to be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access are available.

- That the required date for use of NPI in transactions in this NPRM must not be sooner than the required date for use of NPI in HIPAA transactions. Before NPI can be mandated there must be sufficient time for batch enumeration and data dissemination to become available. We believe that the NPRM date of January 2006 is premature because of non-availability of these NPI system capabilities.

Formulary and Medication History Standards

Medco recommends that the formulary, benefit and medication history messaging standards currently being developed be pilot tested before HHS releases final standards. Vendors should be factored into the regulation process and be encouraged to bring products to market that assist physicians to comply with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered as pharmacies

and pharmacy benefit managers must have systems operational to test prescriptions that comply with new standards.

Medco urges HHS to make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had the most difficult task of trying to resolve inter-governmental differences from across the Federal government in the Addendum to the Electronic Transactions and Code Sets rule. The additional time it took to resolve these differences left inadequate time for the various vendors to work with their customers (the provider and payer communities) to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long, and not conducive to industry usage.

Medication history standards

Medco recommends that private sector development and maintenance and modifications to standards not be hindered by extensive rule making processes.

Medco is concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the privacy rule is powerful privacy protection, the control mechanisms necessary to know what is "minimally necessary" and to prevent more than the minimum necessary in responses to requests for a listing of a patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex.

Current models for retrieving prescription and medical history are developing and are incomplete. For example, patients often use multiple pharmacies thereby rendering prescription records at any one physical location incomplete. Further to the point diagnostic reasons for a prescription may not always be accurate

PROVISIONS OF THE PROPOSED REGULATION

"B. Proposed Definitions"

Medco recommends that the definitions provided in FR 6265 be written more generically without reference to Part D. E-Prescribing regulations and voluntary efforts based on regulations are likely to evolve to Medicaid and other plans, therefore definitions should not be restricted to the single initial plan.

"E - Proposed Standards - Eligibility

Adopt ASC X12N 270/271 where Appropriate. For eligibility inquiry and response, the HIPAA Transactions and Code Sets rule adopts the NCPDP Telecommunication Standard for pharmacy inquiry and the ASC X12N 270/271 for physician and other provider inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

Plans should respond with more than "yes" or "no". In the current HIPAA 270/271 eligibility transaction, a health plan may either provide detailed benefit information or simply respond "Yes, this person has coverage, or No, this person does not have coverage". Physicians need more detail than yes/no and they need the information in a more consistent format. At a minimum, plans should respond whether the patient is covered, and guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. Medco recommends that the requirement for better response information be strengthened

Regulatory Impact Analysis

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2012 with a slightly lesser cut in 2013. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40% less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to help the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless it provides an irrefutable, tangible benefit to their patients and practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of improved efficiency, patient safety and health care quality through electronic prescribing.

Medco believes that e-prescribing offers significant financial and other benefit potential to providers. But that case may not appear compelling to many providers in the financial environment between now and 2014. We recommend that CMS partner with the private

sector in funding development of analysis and educational documentation making that helps providers understand the economic benefits for e-Prescribing.

PROVISIONS OF THE PROPOSED REGULATION

Other

We propose adding the requirement of a Diagnosis on the prescription to the e-prescribing rules. Requiring a diagnosis on the prescription:

- Supports many of the Medicare electronic prescription drug program requirements and in some cases is necessary to achieve the program requirement.
- Complies with HIPPA.
- Supports and is consistent with MMA cost control and quality improvement requirements.

Diagnosis codes support other electronic prescription drug program requirements

The Act requires an electronic prescription drug program to provide for the electronic transmittal of certain information to the prescribing health care professional and to the dispensing pharmacy and pharmacist. The following statute-required information would be greatly facilitated if the diagnosis code was on the prescription:

- Information on eligibility and benefits (including drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) is required by the statute. Diagnosis codes can help determine eligibility for prescription plan coverage. Some prescription drugs have multiple uses, some of which are eligible for coverage under Medicare while others are not. Without knowing the diagnosis, plans and pharmacy benefit programs have limited ability to efficiently determine whether the plan's coverage criteria have been met. Examples of how inclusion of the diagnosis on the script facilitates coverage decisions include:

  Zofran or any anti-nausea or anti-vomiting drug is covered by Medicare under Parts A and B by most plans when used for "medical care and treatment", such as following chemotherapy or for the prevention of post-operative nausea and vomiting. A use usually not eligible for plan coverage is nausea associated with seasickness for an upcoming summer cruise or fishing trip.

  Botox has approved uses for several conditions with doses substantially higher for cervical dystonia than for other medical uses. However, Botox Cosmetic for wrinkles is seldom an eligible plan expense. Since Botox is identical to Botox Cosmetic, it could be used as a cosmetic treatment. Having the diagnosis on the prescription as the representation of the

physician's intended use is an efficient mechanism to determine whether the expense is eligible or ineligible for coverage under the plan.

- Same Drug; Multiple Uses: It is common for one drug to have multiple uses. For each condition, where use is FDA approved or recommended by an authoritative group, the recommended initial dose and the duration of therapy can vary significantly depending on the needs of each patient and on their specific conditions. Without knowing the diagnosis, it is impossible to provide reliable information on dosage adjustments and other important warnings and cautions. Examples include:

  Prilosec: Prilosec has eight approved indications. The recommended dose of Prilosec for an active duodenal ulcer is 20 mg once a day for a period of 4 weeks. Some patients may need an additional 4 weeks. However, if the patient has Zolinger-Ellison Syndrome, the recommended dose is 60 mg once a day, with continuous treatment.

  Coreg: The appropriate dose when used for congestive heart failure would be 3.125 mg twice a day. But if Coreg is used for hypertension, the recommended dose is twice as high.

- Different Drugs, Different Uses, Confusing Names: Sometimes medication is selected in error because the names are similar with slightly different spelling or pronunciation. Diagnosis codes allows prescribers, dispensing pharmacists, Pharmacy Benefit Managers to check the diagnosis code against the dosing specific to the patient's condition. Examples of drugs that have been mixed up include the following:

  Imferon (an iron replacement) and Interferon (for cancer therapy)
  Xanax (for anxiety) and Zantac (for ulcers)
  Celebrex (for arthritis) and Celexa (for depression)
  Quinine (for nocturnal leg cramps and treatment of malaria) and quinidine (for abnormal heart rhythms).

- Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed is required by the statute. Without knowing the diagnosis, accurate information regarding lower cost or therapeutically appropriate alternatives cannot be provided in many cases. In fact, too often prescriptions are written when there is no evidence that the drug is either appropriate or effective. Marketing efforts coupled with new products and more approved indications for an existing product have contributed to prescribing patterns that fall outside reasonable guidelines. There are many possible examples, including:

The patient "asked for it" or "expected it". Antibiotics are often cited as examples.

The medication was selected in error.

The medication was selected as an experimental approach without evidence. Neurontin is an example where aggressive marketing efforts resulted in 78% non-FDA approved use of the drug. There are reports that off-label marketing was often supported with nothing but anecdotal evidence often sponsored or created by the drug company, with little or no hard data. For some conditions they also promoted dosages that exceeded FDA-approved guidelines.

The prescribing physician is involved in research that has not yet been published, but benefits to the patient are quantifiable and substantial. Best practice begins somewhere – and when substantiated as effective and appropriate, sharing with others sooner is to the benefit of all.

- Information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved is required by the statute. The statue recognizes the importance of the medical history and intends to propose standards for communicating medical history at a future date. Clearly, if medical history is important, current medical status (diagnosis) should be an even higher priority.

Diagnosis Code Complies with HIPPA

The statute requires that information shall only be disclosed if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) under the Health Insurance Portability and Accountability Act of 1996. The department of Health and Human Services has confirmed that requiring a diagnosis or diagnosis code on a prescription requires no separate special authorization because it falls within the treatment, payment and healthcare operations category of the privacy rule.

However, there may be specific circumstances under which diagnosis is deemed inappropriate by the prescriber or patient, e.g., when doing so might compromise patient adherence to therapy or confidentiality. Therefore we suggest when it may be inappropriate to include the diagnosis or indication on the prescription, this information can be communicated to the pharmacy concurrent with the prescription being placed (verbally or written separately), or after the drug is dispensed. A concurrent transmission is preferred, as it prevents delay in dispensing and counseling, or the need to address dispensing or counseling errors after the fact.

Diagnosis Codes Supports MMA Objectives

Diagnosis codes supports and facilitates the Medicare Modernization Act's cost control and quality improvement requirements. Specifically the MMA regulations state:

- Each plan sponsor must have established a drug utilization management program, a quality assurance program, a Medication Therapy Management Program and a program to control fraud, abuse and waste.

- A reasonable and appropriate drug utilization management program must include incentives to reduce costs when medically appropriate; maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

- A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

Knowing the diagnosis is key to any utilization management program. Without the diagnosis, presumptions and guess work replace fact-based decision making. In many cases, utilization management programs spend time and money to confirm a diagnosis so that utilization review can be performed. Diagnosis supports and facilitates the MMA objectives and it can reduce the need for prior authorization and other utilization management programs. The diagnosis would illustrate the prescribing physician's intended use and thereby eliminate or reduce the need to contact the physician. An efficient, fact-based process should translate to easier approvals (or denials) of prescription plan coverage with savings in the tens of millions to Medicare and Rx drug benefit plan sponsors.

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April 5, 2005

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Via Electronic Mail

Attention: **CMS-0011-P**

Re: Comments on Proposed Rule: Medicare Program: E-Prescribing and the Prescription Drug Program NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). BCBSA represents the 40 independent Blue Cross and Blue Shield Plans (Plans) that provide coverage to 92 million people – nearly one-in-three Americans – among them approximately one million beneficiaries in Medicare Advantage.

BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries – and also help slow the rate of growth in spending – by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and claims administrators in Medicare Part D.

First and foremost, we urge CMS to change the January 1, 2006 compliance date to give plans the time to build the capacity for e-prescribing and ensure a smooth transition to the national standard. CMS should allow a period of pilot testing before final adoption of standards – as provided for in the statute and as recommended by the Workgroup for Electronic Data Interchange[1] – and a sufficient implementation period after HHS has issued final rules for plans to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the

[1] See Letter to The Honorable Tommy Thompson from the Workgroup for Electronic Data Interchange (WEDI), dated March 8, 2004. WEDI supported and recommended the concept of using pilot implementations for future standards. Piloting identifies flaws that could be corrected before issuing final standards and determines if proposed standards actually accomplish intended goals. *Id.* at page 6.
www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/March82004LettertoDHHS.pdf

Deleted: April 5, 2005

system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

- BCBSA supports CMS choices of ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, many commercial and proprietary e-prescribing systems currently do not use these standards. It will take time to develop and deploy software that uses these standards, time to test these standards, and time to identify and correct any problems integrating 270/271 and NCPDP standards.

- Performance testing is particularly important for the 270/271 standards because relatively few providers are now originating 270 transactions for claims. For example, 2004 data on HIPAA transactions from Blue Cross and Blue Shield Plans' national accounts and traveling members show that 270 transactions comprised less than 2 percent of total HIPAA transactions.

- For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

In addition to changing the compliance date, BCBSA urges CMS to make two other important changes:

- Adopt a broader view of preemption that federal law preempts any state law. CMS's narrow interpretation of preemption could make e-prescribing administratively difficult for providers, pharmacies, and administrators.

- Follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. CMS's proposal unnecessarily regulates entities' internal processes, thus raising the administrative burden of supporting e-prescribing.

We appreciate the opportunity to offer these comments, which we strongly believe will make e-prescribing administratively practicable for providers, pharmacies and claims administrators, thus strengthening the overall Part D benefit. Please find attached more detailed comments, arrayed to follow the issues as presented in the NPRM.

We look forward to continuing to work with you and your staff on this and all other issues relating to the Medicare Prescription Drug Benefit.

Sincerely,

Alissa Fox

Alissa Fox
Executive Director, Policy

Attachment

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April 5, 2005

Blue Cross Blue Shield Association Comments on
"Medicare Program: E-Prescribing and the Prescription Drug Program"
Proposed Rule
NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)
CMS-0011-P

The Center for Medicare and Medicaid Services (CMS) requested that comments be organized by the section of the proposed rule to which they apply, using the specific "issue identifier" that precedes the section: **Background;** and **Provisions**. The order of these comments follows the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on February 4, 2005.

I. Background

State preemption (Page 6258)

Proposed Rule: The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contains specific statutory language on the preemption of State laws that are contrary to the standards or restrict the ability to carry out the Part D benefit and that pertain to the electronic transmission of prescriptions and information with respect to Part D covered drugs. CMS proposes to interpret this preemption of state laws narrowly, finding that it applies only to state laws that are either contrary to the Federal standards or that restrict the ability to carry out the e-prescribing drug program requirements and pertain to electronic prescriptions and information regarding Part D drugs for Part D enrolled individuals.

Issues: Variations in state rules and regulations are ubiquitous. As explained in a separate letter "Comments on E-Prescribing of Drugs and Preemption of State Laws," BCBSA believes that forcing providers, pharmacies, and claims administrators to comply simultaneously with multiple state rules and the federal rule may deter use of e-prescribing, and unnecessarily raise costs and administrative burden.

BCBSA Recommendation: BCBSA believes that CMS should adopt a more expansive view of federal preemption confirming that federal law preempts any state law that would frustrate Congress' policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D.

Criteria for determining foundation standards (Page 6261)

Proposed Rule: The MMA permits HHS to adopt standards as final without pilot testing where the Secretary can determine there is "adequate industry experience" with the standard. The MMA did not define "adequate industry experience." CMS has proposed the following criteria to assess adequate industry experience:

- American National Standards Institute (ANSI) accredited;
- Generally has been implemented in multiple e-prescribing programs with more than one external partner by entities to which the final standard will apply; and
- Recognized by key industry stakeholders as the industry standard.

Issues: We believe that these criteria are necessary – especially ANSI accreditation – but not sufficient to assess adequate industry experience. The HIPAA transaction experience demonstrates that systems and processes vary greatly, especially around key vendor products. Therefore, implementation in "multiple" e-prescribing programs is no guarantee that a standard can go without testing in all settings; for example, systems that work well for a chain pharmacy model may not work well for independent pharmacies or for mail order pharmacies.

BCBSA Recommendation: CMS should seek additional recommendations from stakeholders on how to assess adequate industry experience. CMS's view that there is adequate industry experience for the proposed foundation standards – a view that we question – is indicative of the need for added criteria.

Identifiers (Page 6262)

Proposed Rule: CMS is considering requiring the use of the national provider identifier (NPI) as the provider identifier for an e-prescription under Medicare Part D. The NPI timetable calls for HHS to begin accepting applications from providers for identifiers after May 23, 2005. Use of the NPI is mandatory starting May 23, 2007 (2008 for small health plans).

Issue: At this time, it appears that the NPI will not be universally available for use by January 2006. For HIPAA NPI implementation purposes, industry has proposed a "workaround" that would allow transactions to carry both the old identifier and the new NPI. However, provider and vendor systems that send billing information to the Plans may not be able to carry both the legacy identifier and the NPI by January 2006.

Plans that did not expect to have to be ready to process the NPI until 2007 may begin to receive transactions with the NPI as the only identifier and other transactions with a non-NPI identifier. Depending on the source of the transaction, plan systems would have to process the transaction using the NPI or a legacy identifier – running and maintaining duplicate systems for the interim period. Plans must be given sufficient time to migrate providers from their legacy identifiers to the providers' new NPI. Additionally, the NPI does not support the necessary transmission routing functions of electronic prescribing identifiers. Current identifiers allow for individual prescriber identification and multiple service locations. A single identifier solution for this shortcoming must be developed, assessed and tested.

BCBSA Recommendation: BCBSA urges that CMS move back the January 1, 2006 compliance date to permit additional time for pilot testing and implementation. This would have the added benefit of avoiding the issues created by an early implementation of the NPI for e-prescribing.

We note that the Workgroup for Electronic Date Interchange (WEDI) recommended in a September 30, 2004 letter to Secretary Tommy Thompson that no successful implementation of the NPI could occur in less than 18 months from the time the NPI is available for use, and that

no full-scale implementation should be undertaken without pilot testing the NPI.[1] We would support pilot testing use of the NPI in the e-prescribing context.

Formulary and medication history standards (Page 6263)

Proposed Rule: The NCVHS determined that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer Protocols established by RxHub. On the basis of this determination and other criteria revealed in the proposed rule, CMS is proposing to adopt other standards currently under development by NCPDP as foundation standards.

Issue: Many Plans that intend to offer Part D benefits use commercial or proprietary formulary and medication history messaging protocols dissimilar to those that will be balloted by NCPDP. Thus, adequate industry experience is lacking.

BCBSA Recommendation: CMS should adopt the formulary and medication history standards currently being balloted by NCPDP as initial standards to pilot test and not as foundation standards for required use beginning January 1, 2006.

Proposed foundation standards (Page 6264)

Proposed Rule: CMS proposes to apply the "adequate industry experience" exception to specific standards regarding prescription transmissions between prescribers and dispensers and eligibility inquiries between dispensers and payors and prescribers and payors (NCPDP SCRIPT Standard, Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5.1; and American Standards Committee (ASC) X 12N 270/271).

Issue: BCBSA supports using ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, industry does not have adequate experience because many current commercial and proprietary e-prescribing systems do not use the 270/271 standards. These e-prescribing systems generally provide eligibility information to the pharmacy using the NCPDP telecommunication standard. It will take time to make enrollee eligibility available to physicians using the 270/271 transaction: time for software development; time for deployment; and time to identify and correct any integration problems.

For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

Lack of adequate industry experience may be a particular issue for mail order pharmacies. Communicating eligibility and benefit status to and from a dispensing pharmacy via the NCPDP telecommunications standard is currently a HIPAA required transaction standard for communications with retail pharmacies. But in mail order pharmacies, prescriptions generally arrive via fax and are entered into the mail-order pharmacy's automated fill-order system. Eligibility is determined by checking against enrollee information provided by a plan directly to the mail-order pharmacy and not through an on-line inquiry system built to the NCPDP

[1] *See* "WEDI NPIPAG Recommendations, August 26, 2004," Issues 1 and 3. A copy of this correspondence can be found at http://www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/093004NPIFinalEDJR.pdf .

Telecommunications Standard. These processes operate on computer programs written to code not interoperable with e-prescribing software.

BCBSA Recommendation: While BCBSA supports the selection of specific appropriate standards for e-prescribing functions, we urge CMS to support a period of pilot testing (for at least one year) to ensure that the 270/271 standards will perform as desired when integrated into an e-prescribing systems with the NCPDP Telecommunication standards. Also, we urge CMS to provide for an implementation period (the statutory timetable would suggest 24 months) that gives plans sufficient time to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

II. Provisions

Definitions (Page 6265)

Proposed Rule: CMS proposes the following definition:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

Issue: The definition reflects the narrow state preemption analysis proposed by CMS to govern conflicts with state laws. Under the proposed definition, an e-prescribing program is limited to Part D drugs prescribed for Part D eligibile individuals who are enrolled in Part D Plans. The adopted standards would then apply only to this narrow set of drugs and individuals.

Recommendation: BCBSA recommends that the definition of a Electronic Prescription Drug Program be revised as follows:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Communication in closed networks (Page 6265)

Proposed Rule: CMS would require e-prescribing communications internal to an organization be communicated in compliance with the adopted NCPDP Script standards for e-prescribing for Part D drugs. The NCVHS had recommended that organizations that conduct e-prescribing internally should not be required to convert to the standards to be adopted by CMS for Medicare Part D for prescription communications within their enterprise. CMS notes that the NCVHS recommendation differs from the HIPAA transaction rule requirement that a "covered entity" conducting a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard HIPAA transaction.

Issue: BCBSA is concerned with CMS' decision not to follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. BCBSA's general approach to health information technology is that transaction rules should not dictate internal processing but should ensure standardizing the interfacing between differing organizations' systems for market interoperability.

BCBSA Recommendation: CMS should follow the recommendations of the NCVHS and recognize that the exchange of prescription information within the same enterprise is outside the scope of the MMA requirements.

Backward compatibility (Page 6267)

Proposed Rule: HHS is proposing to consider waiving notice and comment rulemaking when updates or newer versions of standards are "backward compatible" (i.e., entities using the newer version would be able to complete transactions with entities using the the previous version). In this case, CMS would likely permit the version that was previously adopted and the new version as equally compliant at the same time.

Issue: In general, an entity using the older version of a standard cannot process the newer version without further system changes, such as the addition of translation software – even when the newer version does not include substantive changes such as new functions. True backward compatibility occurs when the entity adopting the new version pays for the translation software. However, the CMS definition of backwards compatibility could be construed as absolving the entity adopting the new version of the obligation of paying for that translation software, thus inadvertently penalizing entities that choose to keep the previously adopted standard.

BCBSA Recommendations: CMS should make clear that the obligation to produce transactions that an entity with a previously adopted versions can process lies with the entity that chooses to migrate to the newer version. CMS should not find backward compatibility where no provision has been made in the standard to ensure that entities with previously adopted versions can process those transactions sent from entities using newer versions.

Linking e-prescribing standards updates to HIPAA standards updates (Page 6267)

Proposed Rule: CMS proposes to coordinate the updating process for those e-prescribing standards that are also HIPAA transaction standards.

Issue: Linking the e-prescribing standard update to the HIPAA standards update would provide administrative simplicity for CMS and reduce the compliance burden for the affected industries and covered entities.

BCBSA Recommendation: BCBSA supports having the e-prescribing standards updates tied to the HIPAA updates. This allows entities to monitor one point for future proposed changes. It also avoids getting HIPAA and e-prescribing out of synch and into conflicting requirements.

Compliance date (Page 6267)

Proposed Rule: CMS proposes making compliance with the e-prescribing standards proposed in this rule mandatory on Part D sponsors and MA/PD plans as of January 1, 2006.

Issue: BCBSA believes that January 2006 is not a reasonable compliance date for implementation of these proposed new foundation standards See "Proposed foundation standards" above

BCBSA Recommendation: See "Proposed foundation standards" above.

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Re: Comments on Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 6255 (Feb 4, 2005) [CMS-0011P]

Dear Administrator McClellan:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit comments on the first proposed rule on electronic prescription system standards ("the Proposed Rule") under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the MMA"). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for cures, and are committed to the successful implementation of the Medicare prescription drug benefit.

Introduction

Section 1860D-4(e)(1) of the Social Security Act ("SSA") requires that any electronic prescription ("e-prescription") used to provide Part D covered drugs to a Part D eligible individual meet e-prescription standards developed by Health and Human Services. Additionally, under proposed 42 CFR § 423.159(c), all sponsors of Medicare prescription drug plans must "support and comply" with these e-prescription standards once they take effect.

The Proposed Rule is the first of several anticipated rules that will be used to establish e-prescription standards. It identifies three existing standards that will constitute "foundation" standards for e-prescribing, which will not have to be pilot tested before being adopted as final standards. In general, the MMA calls for e-

prescription standards to be pilot tested during calendar year 2006, before being adopted.[1] Testing is not required, however, "where there already is adequate industry experience with" the standard at issue.[2] Many of the our comments are in response to requests for comments on the standard development process in general, particular standards that will be developed in future rules, and the criteria used to determine whether adequate industry experience exists for a particular standard.

Overview of Comments

Because the e-prescription standards will be developed in a step-wise fashion, it will be critical, from the beginning of the process, to have explicit design principles to guide development of the individual standards. Absent such principles, the standards as a whole may be incomplete, inconsistent or even counter-productive. The first comment presented below ("Design Principles for an E-prescription System") recommends a set of principles to be used for this purpose.

It also will be important to have a clear idea of the number of standards required, and the scope of each standard. If these parameters are not clear, the resulting set of standards may be incomplete. Comments 2 and 3 ("Critical Aspects of An E-Prescribing Transaction" and "Standards Required for an E-prescription System") describe the range of standards required.

To evaluate the e-prescription system, it will be necessary to assess the value of a given standard or combination of standards. The cost of the drugs prescribed under the system is only one element of its value. For example, the extent to which the e-prescription system is accepted and used by prescribers, the time and other resources prescribers and dispensers save by performing essential functions electronically, and the impact on the overall cost of treatment (including a decrease in the cost of non-drug therapies as drug therapies are used more effectively) all will play a role in determining the system's value. A number of these factors are set out in Comment 4 ("Factors To Consider in Assessing Value"). The factors also may be considered to evaluate proposals for individual standards.

The next seven comments are narrower in focus. Comment 5 ("Definition of 'Adequate Industry Experience'") addresses the criteria that should be used to determine whether pilot testing should be suspended for a given standard (i.e., whether the standard should be designated a "foundation" standard), while Comment 6 discusses the proposed NCPDP Formulary and Benefit Standard. Comment 7 addresses whether the e-prescription system should support prior authorization of prescriptions. Comments 8 and 9 address issues that may be

[1] SSA §1860D-4(e)(4)(c)(i).

[2] SSA §1860D-4(e)(4)(c)(ii).

raised by forthcoming standards for drug information and messages, and Comment 10 discusses information about lower cost therapeutically appropriate alternatives. Comment 11 discusses the direct cost of an e-prescription system to pharmaceutical manufacturers (for purposes of determining the cost impact of the proposed rule).

The final three comments concern the process used to develop and implement an e-prescription system. Comment 12 recommends principles for maintaining adequate stakeholder involvement in this process. Comment 13 discusses the use of formal rulemaking, while Comment 14 discusses the limited circumstances under which standards may be updated without formal rulemaking.

Comments

COMMENT 1: DESIGN PRINCIPLES FOR AN E-PRESCRIPTION SYSTEM
(Responds to BACKGROUND, Sections F and G)

We believe that an e-prescription system should be designed to embody the following principles.

1. **An e-prescription system should be designed to improve patient care and strengthen the physician-patient relationship.**

   - ***Put the patient first.*** The system should be designed to ensure patient safety (for example, by helping to avoid adverse drug-to-drug interactions), improve the quality of care, and promote the efficient delivery of prescription drugs.

   - ***Protect patient privacy.*** Privacy and confidentiality are important concerns throughout the health care delivery system. An e-prescription standard should ensure adequate security and privacy measures.

   - ***Promote physician-patient communication.*** The system should facilitate a dialogue between the provider and the patient at the point of care. Patients have individual clinical needs, life circumstances, and personal values that influence their medical care. A dialogue at the point of care will help the physician to choose an appropriate drug therapy and increase patient compliance with that therapy.

   - ***Preserve the physician's role.*** The system should support the clinical judgment of physicians (and other drug prescribers). Preserving the physician's autonomy to select the right therapy for a patient is critical to preserving the physician-patient relationship and achieving quality medical care.

2. **An e-prescription system should provide information when it is needed.**

   - ***Provide the information needed by physicians.*** An e-prescription system should provide physicians with the information needed to discuss drug therapy with the patient at the point of care. The system also should allow the physician to perform functions that will determine what drugs are available, such as prior authorization and eligibility verification, at the point of care.

   - ***Provide the information needed for beneficiary protection.*** An exceptions and appeals process is an important protection that allows beneficiaries to access needed medications. An e-prescription system should enable the beneficiary to receive immediate notice of the right to request an exception or appeal, and the information required to do so.

   - ***Work with other electronic health information systems.*** An e-prescription system should be compatible with the electronic health record (EHR) systems that currently are being refined and standardized. This would allow information to be exchanged between the two systems. For example, the e-prescription system could import information about prior drug therapies from an individual's EHR to add to the individual's medication history.

3. **An e-prescription system should be designed to reduce the overall cost of care.**

   - ***Consider the full range of cost savings.*** The e-prescription standards should promote a system design that serves to maximize all the potential savings available through the improvements in patient safety, quality of care and cost-effectiveness. For example, using drug therapies more effectively will reduce inpatient admissions, which results in cost savings throughout the health care delivery system. Eliminating fraud and abuse likewise will reduce overall health care costs.

   - ***Provide value to all parties using the system.*** The e-prescription standards should not impose an undue administrative burden on health care professionals or dispensing pharmacies and pharmacists, or otherwise discourage them from using the e-prescription system.

   - ***Cover the entire prescribing process.*** The system should enable system participants to perform all of the significant steps in the prescribing process (such as prior authorization) more efficiently. Simplicity is likely to be a significant factor in determining whether prescribers embrace e-prescribing; they are less likely to do so if they still must resort at times to an alternative system that is not available at the

point of care. The value of the system also would be enhanced if it supported "Fill Status Notification" transactions that allow prescribers to determine whether prescriptions that have been written actually have been filled and received by patients.

COMMENT 2: CRITICAL ASPECTS OF AN E-PRESCRIBING TRANSACTION
(Responds to BACKGROUND, Sections F and G)

E-prescribing standards may regulate three different aspects of an e-prescription transaction: (1) content, (2) integrity and (3) display.

1. ***Content*** refers to the types of information contained in the transaction, its format and (when appropriate) the use of standardized codes for certain types of information. Content issues include the following:

   - What types of information are needed to support all of the functions accomplished through the transaction? Is all of the information required to support the function being conveyed?

   - Is the information suited to its intended audience (prescriber or dispenser)?

   - Is the information ambiguous or misleading?

2. ***Integrity*** refers to the accuracy and reliability of the information being conveyed. Integrity issues include the following.

   - Is the information complete? The system should provide all of the information of a given type that is required for the prescriber or dispenser to perform the function at issue. It is especially important that information directly involved in treatment (such as medication history and medical history) be complete even though it may be drawn from a number of different sources.

   - Is the information up-to-date? This requirement also will vary with the type of information and the purpose for which it is used. For many types of information directly used in treatment, this is an especially important concern.

- What is the source of the information? If the information incorporates judgments, is the source knowledgeable enough and objective enough to make accurate judgments?

- Should the information be certified by a third party, or produced according to a process set forth by CMS, in order to ensure its accuracy? Relying on existing third-parties with the expertise and objectivity to perform this function could simplify the standards and the standard development process.

3. ***Display*** refers to the manner in which the transaction is presented to the prescriber or dispenser who will be using it; it includes both the appearance and arrangement of the information in the display (including the use of pop-up menus and other devices that emphasize certain information) and the steps that the prescriber or dispenser must follow to navigate through the information. Display issues include the following.

   - Could the manner in which the information is displayed inappropriately influence the prescriber or dispenser who receives it? For example, does the system initially display only certain drugs in the formulary to reduce the likelihood that the prescriber will evaluate (and possibly choose) other clinical options?

   - Does the manner in which the information is displayed place a burden on the prescribers or dispensers who use the system? For example, is it more technologically cumbersome or inconvenient to prescribe certain drugs because the prescriber must navigate through more screens or respond to additional prompts?

   - Does the display impede decision-making (prescriber, patient)? For example, do pop-up messages repeatedly appear and disrupt the prescriber's normal decision-making process?

   - Is one display suitable for all users or should users control the display to some extent?

For several reasons, the standards proposed in the Proposed Rule address content issues rather than integrity or display issues. This focus is appropriate: the transactions governed by these standards convey objective information rather than judgments or assessments, and the information in each transaction is derived from a single source. As a result, concerns with the integrity of the information are minimized. The information conveyed also is relatively simple and straightforward, which likewise minimizes concerns about its display.

Other standards required for a fully functional e-prescription system, however, will raise integrity and display issues. This is especially true of standards that provide information integral to the prescribers' deliberations (such as medication and medical history, as well as messaging), which typically will convey judgments of some kind. Consequently, even at this early stage of the process, it is appropriate to consider how those concerns will be addressed and integrity and display will be regulated.

As indicated in the appendix to these comments, parties testifying before the National Committee on Vital and Health Statistics (NCVHS) already have been looking ahead to these issues. Among these looming issues are the following.

- Will the NCVHS evaluate and make recommendations concerning integrity and display issues?

- Will candidate standards from existing standard development organizations address integrity and display issues? If these candidate standards do not (possibly because the organizations historically have focused exclusively on content concerns), how will CMS develop integrity and display standards? Will the agency develop the necessary standards itself or look to other organizations that have been more concerned with such issues?

- Are traditional standards the best approach to regulating integrity and display concerns? Alternatively, would third-party review and certification, or standards that limit the process by which the information is developed or compiled, be better than a prescriptive standard?

COMMENT 3: STANDARDS REQUIRED FOR AN E-PRESCRIPTION SYSTEM

(Responds to BACKGROUND, Sections F and G)

The following table indicates the number of distinct standards required to establish an e-prescription system with the range of functions contemplated by the MMA. The Proposed Rule identifies foundation standards for the first two types of information, prescription information and eligibility information.

Our comments pay special attention to the forthcoming standards required to regulate Drug Information and Messaging. While not discussed in detail in the Proposed Rule, these standards will be relatively complex and raise special concerns about the integrity of the information that is conveyed and the way this information is displayed. Consequently, even at this early point in the process, it is appropriate to think about the general approach that should be followed to develop these standards.

Table: E-Prescription Standards Required

Type of Information Transmitted	*Existing Standard*	*Content Concerns*	*Integrity Concerns*	*Display Concerns*
Prescription – SSA § 1860D-4(e)(2)(A)	NCPDP SCRIPT	No	No	No
Eligibility – SSA § 1860D-4(e)(2)(A)	X12N 270/271	No	No	No
Telecommunications –	NCPDP Telecomm'ns	No	No	No
Formulary & Benefit Coverage – SSA § 1860D-4(e)(2)(A)	NCPDP F&B (proposed)	Yes	Yes	Yes
Prior Authorization – SSA § 1860D-4(e)(2)(A)	No	Yes	No	Yes
Medication History – 70 Fed. Reg. 6263	NCPDP Med. History(proposed)	Yes	Yes	No
Medical History – SSA § 1860D-4(e)(2)(B)	No	Yes	Yes	No
Drug Information – SSA §1860D-4(e)(2)(A)(i), (3)(C)(iii)	No	Yes	Yes	Yes
Messaging – SSA § 1860D-4(e)(3)(D)	No	Yes	Yes	Yes

COMMENT 4: FACTORS TO CONSIDER IN ASSESSING VALUE
(Responds to BACKGROUND, Sections F and G)

Both during pilot testing and once the e-prescription standards are finalized, CMS should collect and evaluate data used to estimate the value added by the e-prescription system. Value will be added not only by reducing the cost of prescriptions but by improving the quality of care and the overall efficiency of the prescription process. It is important to consider the following types of data, which would be overlooked if prescription drug "line item" costs are regarded as the sole measure of value:

- The level of use by (and direct feedback from) prescribers. Prescribers are not required to use the e-prescribing system and presumably do so only if it provides advantages over non-electronic methods.
- Prescribers' and dispensers' estimates of cost savings.
- Positive feedback from patients (for example, reports of improved dialogue with providers about drug therapies).

- Improved persistence and adherence to drug therapies.
- The reduction in medication errors (include undesirable drug-to-drug interactions).
- The reduction in communications about prescriptions outside of the e-prescription system (such as telephone inquiries from dispensers to prescribers).
- The extent to which essential steps in the prescribing process may be performed through the system, without recourse to alternative methods (such as telephone inquiries).
- Ways in which the system may be used to monitor and combat fraud and abuse.
- The extent to which the system allows access to relevant data for legitimate research activities.
- The change in total treatment costs (including reduced non-drug treatment costs due to the more effective use of drug therapies).

COMMENT 5: DEFINITION OF "ADEQUATE INDUSTRY EXPERIENCE"
(Responds to BACKGROUND, Section F)

E-prescription standards generally are subject to pilot testing. This requirement is waived, however, if there is "adequate industry experience" with the standard at issue. The Proposed Rule proposes the following criteria for assessing whether adequate industry experience exists.

(1) The standard is American National Standards Institute (ANSI) accredited;

(2) The standard generally has been implemented by the entities that will be subject to it once it is adopted for e-prescribing purposes;[3]

(3) The standard is recognized by key industry stakeholders as an industry standard.

While CMS has the authority to designate foundation standards, it should not do so mechanically. Identifying foundation standards can expedite implementation if those standards in effect have already been tested. Weakening these criteria would only delay implementation by preventing needed testing from taking place.

[3] Because this requirement is intended to identify standards which have been implemented successfully in a context comparable to e-prescribing, these entities as a whole must implement the standard in multiple programs, each with multiple participants. 70 Fed. Reg. 6261.

Consequently, we believe that these criteria should be not only maintained but strengthened. Specifically:

(1) The ANSI accreditation requirement should be maintained even if there are no ANSI accredited candidates for a particular standard. As the Proposed Rule notes, the ANSI accreditation process is open to all entities that may be regarded as stakeholders in the e-prescription system. In addition, the ANSI standard development process is consensus based, which encourages broad participation in standard development. Abandoning the requirement increases the risk that some stakeholders may not have a meaningful opportunity to participate in the development process.

(2) The standard should not only have been implemented but have been used for a volume of transactions that suggests that it will be capable of functioning in a fully deployed e-prescription system. In other words, the transaction volume (while possibly less than anticipated for e-prescribing) should suggest a mature, commercial program and not an experimental program of limited scope. In addition, CMS should consider the length of time that the standard has been implemented.

(3) CMS should consider whether all of the possible stakeholders in the e-prescription system (and not just a small group of "key" stakeholders) have embraced the standard. To begin with, it is unclear how CMS will determine what "industries" to consider. Entities other than prescribers and dispensers will play a meaningful role in supporting the e-prescription system. Medication and medical information, for example, may have to be collected from sources that are not serving as prescribers or dispensers, but will have to accommodate the standards for that information to perform their role effectively. Perhaps most importantly, the e-prescription system will have to be compatible with electronic health record systems that have yet to be fully deployed. Incorporating standards that are accepted across health care industries increases the chance that an e-prescription system will be compatible with other electronic health information standards.

There is an advantage to designating foundation standards when testing is simplified as a result. This usually occurs when the standard at issue is self-contained. The X12N 270/271 standard, for example, fully describes the eligibility inquiry and response transactions without referring to other standards. As a result, if they are designated as foundation standards, there is no need to test the eligibility transactions at all. If a given standard is only one of several that govern a particular transaction, however, designating it as a foundation standard will have a very limited impact on testing. The transactions will still have to be tested to determine whether the other standards are appropriate and interact effectively. The development process may even be complicated because the foundation standard is finalized early and cannot easily be modified to fit better with the others.

COMMENT 6: THE PROPOSED NCPDP FORMULARY AND BENEFIT STANDARD
(Responds to BACKGROUND, Section F)

According to the MMA, e-prescriptions should accommodate information on "the availability of lower cost therapeutically appropriate alternatives (if any) for the drug prescribed." As discussed in detail in Comment 10, "Information on Lower Cost Therapeutically Appropriate Alternatives," the e-prescribing system will provide several types of information (such as the detailed information provided about additional drugs) that will be helpful to a physician who is evaluating different drug options for a patient.

Attempts to include additional statements about alternative drugs would not be helpful, and may even have negative consequences. In light of these concerns, we recommend that the version of the Formulary and Benefit Standard adopted by CMS not include the "Formulary Alternatives List" contained in the current NCPDP version. The "Formulary Alternatives List" could be used to suggest – erroneously – that certain drugs are interchangeable. Use of this list is not regulated by the standard itself.

COMMENT 7: PRIOR AUTHORIZATION
(Responds to BACKGROUND, Section G)

If a prior authorization requirement is imposed upon a particular drug, the e-prescribing system should allow a prescriber to request prior authorization and learn, at the point of care, whether that request is successful. The MMA requires that the system avoids placing any undue burden on the prescriber, and for good reason: simplifying the prescribing process will promote clinically appropriate decisions. But the value of an e-prescribing system will be compromised if prescribers are forced to use an alternative method for prior authorization that is not available at the point of care.

To ensure e-prescribing's success, it is critical that the final system fully supports electronic prior authorization for those drugs subject to the requirement. Because this would be a significant advance over existing systems, electronic prior authorization should be included and tested in the 2006 pilots. From the time it first becomes fully operational, for those drugs subject to prior authorization requirements, the e-prescribing system should allow prescribers to perform the entire prior authorization process through the system.

Since full support for prior authorization is not possible at this time, the capabilities of the proposed foundation standards adopted prior to pilot testing should be utilized to provide some degree of support for prior authorization. Specifically, the proposed NCPDP Formulary and Benefit

Standard contains 100- and 200-character free text fields ("Message - Short" and "Message - Long") and a resource link field, which are intended to support several different functions. These fields can be used to provide drug-level information on prior authorization requirements. The resource link field could also be used to provide the prescriber with a hyperlink to a web site used to complete and submit the prior authorization request. CMS should require all plans that use the Formulary and Benefit Standard to use these fields to provide coverage-specific and drug-specific information for all drugs that require prior authorization. We emphasize, however, that this approach is only an interim solution to be used while full support for electronic prior authorization is being developed through pilot testing.

COMMENT 8: STANDARDS FOR DRUG INFORMATION
(Responds to BACKGROUND, Section G)

All of the drug information required by entities using the e-prescription system, including (but not limited to) information on drug-to-drug interactions, can be derived from drug labels that meet the requirements proposed by the Food and Drug Administration (FDA). On December 22, 2000, FDA proposed a new rule to change the content and format of the drug label, which has been under development since that time.[4] The final version of this rule should result in a more user-friendly presentation of important information that physicians need.

These new requirements dovetail with initiatives to develop an electronic format for drug labels. For the past five years, PhRMA has led an initiative to deliver electronic drug labels to dispensing sites. At the current time, FDA regulations require paper drug labels to be affixed to all package units delivered to the pharmacy.[5] These labels are unwieldy and there is no guarantee that they contain the most current information on the drug. Through the HL-7 ANSI-accredited standard development organization, the Structured Product Label (SPL), which will meet the requirements of the new FDA rule, is under development; Version 1.0 was approved late last year and Version 2.0 will be coming up for balloting this spring. A final SPL standard will provide the impetus for industry to submit labels to FDA in electronic format.

FDA presently is constructing an information technology system that will expedite the transmission and review of electronic drug labels. Part of this will be a new initiative that will post the most current drug labels on the National Library of Medicine website. In addition to promoting the general goal of improving the safety and quality of medication management, this new initiative will provide a repository for label information that can be utilized by an e-prescription system.

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[4] 65 Fed. Reg. 81082 ("Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels").

[5] 21 C.F.R Sec. 201.100.

Given that the SPLs will be readily available (to other electronic health care systems as well as the e-prescription system) and meet the most up-to-date label requirements, we recommend that drug information available through the e-prescription system consist of the drug's SPL. To avoid confusion, information should not be added or reformatted.[6] This requirement ensures that the information will be accurate, appropriate and displayed in a manner that prescribers will understand. It also ensures compatibility with other electronic health information systems that utilize SPL information.

COMMENT 9: STANDARDS FOR MESSAGING
(Responds to BACKGROUND, Section G)

Messaging raises a wide range of issues. Messaging could be a valuable tool for ensuring that prescribers have appropriate information about drug choices, such as warnings about adverse drug interactions and instructions helpful in selecting drugs for an individual patient (for example, whether drugs should be taken with food). Given the MMA's restriction on advertising, however, messaging raises content issues. Because these messages may contain judgments or compilations of information, integrity issues also arise. Finally, because the way that information is presented strongly affects its impact (imagine, for example, a pop-up message that requires several steps to close) there also will be issues about how the information is displayed.

It is critical that the standards embody the MMA's prohibition on commercial messaging. Messages may contain only information that "relates to the appropriate prescribing of drugs," including information intended to reduce medication errors and adverse drug interactions, and "improve medication use" (such as information provided under quality assurance measures or systems established pursuant to MMA Section 1860D-4(c)(1)(B)). The e-prescription system may not be used "as a marketing platform or other mechanism that could unduly influence physicians' clinical decisions."[7] Instead, providers should have "ready access to neutral and unbiased information on the full range of covered outpatient drugs available."[8]

Messaging requirements will vary depending on the timing and direction of the message. Given the MMA's restriction on advertising, it is especially important to scrutinize messages directed to the prescriber. Messages that appear before the

[6] Information presented in addition to the SPL should be regarded as one or more messages and must satisfy the standards that apply to messages. This distinction between drug information, defined simply by reference to a drug's SPL, and messaging will simplify the standards without limiting the total amount of information that can be provided.

[7] Conference Report at 455 (for real-time transmission); Letter from Senator Grassley to NCVHS, *Implementation of the Medicare Modernization Act (MMA) Electronic Prescribing Program* of 7/26/04.

[8] Id.

prescriber begins the decision making process (for example, those that appear as soon as the system is activated) are less likely to convey specific information used in prescribing. These messages should be regulated carefully to prevent advertising. Messages contained in a "Change Request" transaction sent to the prescriber after he or she has transmitted a prescription also are suspect. Unless the transaction identifies an error (or potential error, such as an undesirable drug interaction), it likely is intended only to pressure the prescriber to change his or her earlier drug decision.

Messaging standards also may distinguish several different types of messages based on the information they contain. For example, messages that convey warnings about drug interactions or possible allergic reactions could always be displayed in a way that would be certain to attract attention, such as pop-up windows. Prescribers would be free, however, to control how messages that contain less critical information are displayed or even to suppress them. (Prescribers are less likely to use the system if they expect to be confronted by a stream of inconvenient or inappropriate messages.)

These are only preliminary observations; the process of developing appropriate messaging standards is just beginning. To avoid confusion, however, messages should not be allowed in e-prescription transactions, even during pilot testing, until adequate standards for the content, integrity and display of these messages have been developed. These will be wholly new standards and, once developed, they should be pilot tested carefully.

As CMS speakers at the March 1, 2005 Open Door Forum on E-Prescribing indicated, some of the steps a plan could take influence or develop a messaging system—for example, contracts with software vendors affect messaging—should be regulated as marketing practices. That type of regulation and standards governing the content, integrity and display of the messages are complimentary and equally important. Ongoing regulation of marketing activities would prevent a plan from establishing an infrastructure in which advertising could exist. The messaging standards themselves, however, will still be needed to provide clear and detailed guidance on what information messages can contain and how they can appear.

COMMENT 10: STANDARDS FOR INFORMATION ON LOWER COST THERAPEUTICALLY APPROPRIATE ALTERNATIVES
(Responds to BACKGROUND, Section G)

According to the MMA, e-prescriptions should accommodate information on "the availability of lower cost therapeutically appropriate alternatives (if any) for the drug prescribed." The e-prescription system will provide several types of information to help a physician identify drug treatment options. The first is information about the individual drugs. As recommended in these comments, the system should provide access to Structured Product Labels (SPLs) that contain

all of the information that soon will be required by the FDA.[9] The SPL will provide information about the uses and efficacy of the drug, various drug properties (such as absorption, bioavailability and route of elimination) and drug-to-drug interactions. Using SPLs as the source of this information ensures that physicians will receive important drug information in a familiar and user-friendly format.

The second type of information is the formulary design itself. The formulary classifies drugs based on properties at a population level, while cost-sharing tiers provide information about costs. The judgments reflected in the formulary have been made by the plan's Pharmacy and Therapeutics Committee (P&T Committee). Specific requirements concerning the composition and conduct of P&T Committees are designed to ensure that these judgments are deliberate and based upon relevant clinical evidence. By making formulary information available to physicians, the e-prescription system will be providing population-level information about "lower cost therapeutically appropriate alternatives (if any)."

A symbol incorporated into the information about a brand-name drug that indicates that an AB-rated generic form of the drug exists also would be helpful to physicians. From a physician's perspective, these symbols would be easy to understand and unambiguous; for system designers, they would be easy to develop and implement. They could be used both in the system used for pilot testing and in the final version of the e-prescription system.

All of the information discussed so far will be helpful to a physician who is evaluating different drug options for a patient. Further attempts to identify specific therapeutic alternatives, however, would not be, and risk overriding the carefully crafted P & T Committee structure and role. There is no generally accepted definition of a "therapeutically appropriate alternative," and it is unclear just what considerations would determine which drugs are assigned this label.[10]

Even drugs with the same mechanism of action will differ in a number of ways that may be clinically significant for a specific patient.[11] These differences include but are not limited to dosing, drug-to-drug interactions, absorption (the route by which the drug moves toward the intended receptors), bioavailability (the amount of the drug that is available at the intended receptors), metabolism, route

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[9] For a more detailed discussion of this recommendation, see Comment 8, "Standards for Drug Information."

[10] Pharmaceutical manufacturers may not state that a drug is comparable to or better than another drugs unless they have specific information on this point that is accepted by the FDA, and such statements themselves are subject to FDA regulation. To ensure its validity, any claim that two drugs are therapeutically appropriate alternatives should be subject to standards of review that are at least this high.

[11] Due to these differences, a drug does not receive FDA approval because it is uses the same mechanism of action as another drug that has been approved. Extensive clinical trials are necessary to demonstrate the safety and effectiveness of the new drug.

of elimination (the route by which the drug is eliminated from the body, for example liver or kidney), indications, contraindications and side effects. In many cases, these differences will be dispositive in choosing a drug for a particular patient. For instance, a patient taking several drugs metabolized through the cytochrome P450 isoenzyme pathway may have difficulty with an additional drug metabolized through the same pathway, leading a physician to select a drug from the class that is metabolized through a different pathway. Additionally, drugs that appear comparable when evaluated at the population level display significant differences in effect at the subpopulation or individual level. [12]

Moreover, the issue of lower cost is itself highly uncertain, with results potentially varying widely based on whether the measure of cost is unit cost of the medicine, total cost of a course of medication therapy, total cost of a course of therapy to which a patient adheres, or total health care costs over varying periods of time.

As noted above, the MMA and the final Part D rule contain detailed requirements concerning the role, composition and procedures of P&T Committees and committees operating under these rules essentially present their view of lower cost therapeutic alternatives at the population level in structuring formularies. Inconsistent claims about drug alternatives developed outside of the P&T Committee's formulary development process risk undermining the committee's role and determinations.

In light of these issues, we recommend that the version of the Formulary and Benefit Standard adopted by CMS not include the "Formulary Alternatives List" contained in the current NCPDP version. The "Formulary Alternatives List" could be used to suggest – erroneously – that certain drugs are interchangeable. Use of this list is not regulated by the standard itself.

Showing two drugs as members of the same drug class also may imply – again, incorrectly – that they are equivalent. This implication would be confusing; as mentioned above, even drugs that are comparable in some respects may be significantly different in a number of others. To prevent what in effect are unregulated claims about therapeutic equivalence, we recommend that the CMS limit the taxonomies that may be used to classify drugs for e-prescription purposes. For example, CMS could establish a list of acceptable taxonomies (possibly those currently being used in e-prescribing software).[13] In addition, any

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[12] See, e.g., Haiden Huskamp, "Managing Psychotropic Drug Costs: Will Formularies Work?" *Health Affairs* 22:5, 84-96, September/October 2003; William Evans and Howard McLeod, "Pharmacogenomics – Drug Disposition, Drug Targets, and Side Effects," *New England Journal of Medicine,* 348, 538-49, February 6, 2003.; and David Nash *et al.*, "Why the Elderly Need Individualized Pharmaceutical Care," Office of Health Policy and Clinical Outcomes, Thomas Jefferson University, April 2000.

[13] Present-day e-prescription software incorporates taxonomies that are used to organize information about specific drugs by drug class. These taxonomies are chosen by the software vendor and usually drawn from a handful of widely used taxonomies (such as those developed by FDB, MediSpan or Multum). Rather than being part of the data stream transmitted to the

e-prescription system that classifies drugs should provide ready access to drug information, which will indicate the similarities (and dissimilarities) that exist between the drugs in each class.

COMMENT 11: DIRECT COST OF AN E-PRESCRIPTION SYSTEM TO PHARMACEUTICAL MANUFACTURERS
(Responds to IMPACT ANALYSIS, Section F)

In its current form, the Proposed Rule appears to have little direct cost impact on pharmaceutical manufacturers. Manufacturers will not be directly involved in the transactions governed by the standards identified by this rule. Consequently, there should be no need to implement or otherwise adjust to those standards.

Other e-prescribing standards, however, may have a significant impact. For example, manufacturers will soon be making a substantial investment both to comply with the anticipated Food and Drug Administration (FDA) rule on the content and format of drug labels and to implement the electronic Structured Product Label (SPL) that currently is under development.[14] If e-prescribing standards required manufacturers, either directly or indirectly, to compile information of a type or in a format other than that required for the SPL, manufacturers will be faced with the additional cost of meeting a second, possibly inconsistent standard. To assess the cost of e-prescribing accurately, CMS should continue to inquire about the possible cost to manufacturers as each e-prescribing standard is announced.

COMMENT 12: PRINCIPLES FOR ENSURING ADEQUATE STAKEHOLDER INVOLVEMENT
(Responds to BACKGROUND, Section F)

The MMA's e-prescription system promises higher quality medical care with fewer prescription errors and lower medical costs. It also will serve as a model for similar systems including e-prescription systems used outside of Medicare. For both of these reasons, it is important that the MMA's system be designed well.

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prescriber, this information typically is contained in support files stored on the device used for e-prescribing, which are updated periodically.

[14]The new FDA requirements have been under development since December 22, 2000, when FDA first published its proposed rule on the topic (65 Fed. Reg. 81082, "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels"). The SPL is being developed through HL-7, an ANSI-accredited standards organization. Version 1.0 was approved late last year; Version 2.0 will be coming up for balloting this spring. The SPL standard will provide the impetus for industry to submit labels to FDA in electronic format.

The e-prescription system contemplated by the MMA is more sophisticated than any current e-prescription system, and adequate standards do not exist for many of its components. The key to designing a successful system is input from stakeholders of various types, with different expertise and insights. The following principles would help CMS to create an infrastructure that enables stakeholders to play a meaningful role in the development process.

- ***Create and publicize a blueprint for the e-prescription system.*** This system blueprint would identify the different standards that will be required and the scope of each standard. Although it would be difficult to predict the timing of each standard precisely, the blueprint should indicate the sequence in which the standards would be developed and any events that must take place before a particular standard could be developed (for example, the release of NCVHS recommendations concerning the standard). Step-wise development is far easier if all stakeholders understand what steps will be involved. This system blueprint will enable stakeholders to predict when input of various types is appropriate, and help CMS to ensure that sufficient time and attention are allocated for each system component.

- ***Provide clear and consistent guidance.*** E-prescribing rules and standards issued by HHS should be unambiguous, easy to understand, and consistent. The guidance should address all obvious areas of concern, such as commercial messaging, patient privacy, and access to necessary medical information.

- ***Engage all stakeholders.*** Physicians, pharmacists, patients, software vendors and all other entities affected by the rules and standards should be given an opportunity to comment upon them before they are finalized. Providing all of these stakeholders with an opportunity to be involved in standard development will maximize the chance of a positive response to the final standards. Once the rules and standards are finalized, the stakeholders should be given adequate time to implement them.

- ***Promote pilot-testing.*** Although standards may be commonly used and therefore considered well established, they should be pilot-tested prior to adoption. This testing will smooth the implementation process; using familiar standards together raises issues that did not exist when the standards were used separately, and even commonly used standards may be new to a significant number of stakeholders. CMS should elicit stakeholder input on the steps involved in testing as well as the standards to be tested. Testing should involve the Medicare population and the prescribers and dispensers who serve them.

- ***Be proactive about coordinating the activities of different groups within HHS.*** Various groups within HHS should work together to identify and resolve issues (e.g. relating to patient privacy) raised during the development of the e-prescribing standards. For example, issues surrounding the use of e-prescription data for legitimate research activities should be resolved well before the system is operational.

COMMENT 13: USE OF FORMAL RULEMAKING IN THE DEVELOPMENT PROCESS
(Responds to BACKGROUND, Section F)

CMS states in the Proposed Rule that "[f]inal standards are standards that would be adopted in regulations through the rulemaking process," and include standards adopted through pilot testing as well as those for which CMS determines pilot testing is unnecessary.[15] We understand this statement to mean that CMS will adopt all final e-prescribing standards through notice and comment rulemaking, consistent with its approach to establishing the foundation standards.

We strongly support this approach. In addition to being consistent with the e-prescribing provisions of the MMA and rulemaking requirements under the Administrative Procedure Act (APA), adopting e-prescribing standards through notice and comment rulemaking will allow for robust input from all stakeholders in the health care system, thereby maximizing the potential for a successful e-prescribing program.[16]

We also recommend that CMS use notice and comment rulemaking to develop the initial standards for pilot testing. Because pilot testing is necessary for any standard (other than those for which there is "adequate industry experience"[17]) to become a final standard, the selection of standards for pilot testing is of critical importance. CMS therefore should ensure that all interested parties have ample opportunity to suggest standards for pilot testing and to comment on those that CMS itself proposes. In addition, a description of the results of the pilot testing (and CMS' interpretation of those results) should be publicly available when CMS elicits comments on the rules that would finalize the e-prescribing standards.

Finally, we recommend that CMS use notice and comment rulemaking to determine whether there is "adequate industry experience" for a standard such that pilot testing is unnecessary. This would ensure that all participants in the

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[15] 70 Fed. Reg. 6258.

[16] *See* SSA § 1860D-4(e)(3)(A) (providing that CMS "shall provide . . . for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs") (emphasis added); § 1860D-4(e)(4)(D) ("[b]ased upon the evaluation of the pilot project . . . , [CMS] shall promulgate uniform [e-prescribing] standards") (emphasis added).

[17] *See* SSA § 1860D-4(e)(4)(C)(ii).

health care system have an opportunity to provide CMS with their assessment of the degree to which standards have been adopted, and thus foster sound determinations concerning where pilot testing is appropriate.

COMMENT 14: UPDATING STANDARDS WITHOUT FORMAL RULEMAKING
(Responds to BACKGROUND, Section F)

In the Proposed Rule, CMS states that it will adopt updated versions of e-prescribing standards by publishing a notice in the Federal Register incorporating the updated standards by reference.[18] CMS indicates it will use notice and comment rulemaking to update e-prescribing standards where "the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction."[19] CMS states that it would "consider waiving" notice and comment rulemaking where updates or newer versions of a standard do one of the following:

1. "correct technical errors";
2. "eliminate technical inconsistencies"; or
3. "add functions unnecessary for the specified e-prescribing transaction."[20]

We agree that under certain circumstances, it might be "unnecessary" and "contrary to the public interest" to delay adoption of e-prescribing standard updates to allow for prior notice and comment.[21] We offer the following recommendations to ensure that the regulatory update process comports with the APA and ensures appropriate stakeholder input.

First, rather than the three categories specified above, CMS should provide that notice and comment rulemaking would be waived only for updates that CMS determines will not impose a material new compliance burden for regulated entities. Because the subject of e-prescribing standards is inherently "technical," it may not be particularly useful to focus on assessing whether updates to standards "simply correct technical errors or eliminate technical inconsistencies."[22] It is possible for updates seemingly making only "technical"

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[18] 70 Fed. Reg. 6267.

[19] *Id.*

[20] *Id.* CMS further states that "in the later case" (which we presume to refer to cases where an update adds functions unnecessary for the transaction), it "likely" would adopt both the previous standard and the new standard, so that adherence with either version would constitute compliance with the standard.

[21] 5 U.S.C. § 553(b)(B) (providing that notice and comment rulemaking may be waived where an agency for "good cause" finds that notice and comment would be "impracticable, unnecessary, or contrary to the public interest," and sets forth such finding in the rule).

[22] *Id.*

changes to entail material compliance burden for plans and providers, and thus to necessitate public comment prior to their adoption.[23] Therefore, it is more appropriate to focus on determining the likelihood of an updated standard imposing new obligations on regulated entities, rather than on whether the update makes "technical" changes or corrections.[24]

Second, CMS should specify that any updates or revisions not subject to prior notice and public comment will be adopted through an interim final rule with comment. CMS's determination that an update or revision does not impose material new compliance burdens should be sufficient to enable the agency to adopt the update without prior public comment. In order for the updated standard to be binding, however, it would need to be adopted through an interim final rule or other "legislative" rule.[25]

Moreover, the interim final rule process would provide an important safeguard in situations where CMS underestimates the impact of an update on the regulated community, or otherwise mistakenly assumes it to be small or uncontroversial. Similarly, it would give stakeholders an opportunity to submit comments advising CMS of a lack of industry experience with an updated standard that would call for pilot testing.[26] An interim final rule that contains a clear explanation (as required under section 5 USC § 553(b)(B)) of why CMS believes the update should not be subject to prior notice and comment, and a subsequent public comment period for stakeholders to respond to this determination, would ensure that CMS has the benefit of input from the full range of parties who would be affected by the adoption of the updated or revised e-prescribing standard.[27]

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[23] *See, e.g.*, Hemp Industries Ass'n v. DEA, 333 F.3d 1082, 1087 (9th Cir. 2003) ("Legislative rules . . . create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress," and "[a]n agency can issue a legislative rule only by using the notice and comment procedure described in the APA, unless it publishes a specific finding of good cause documenting why such procedures 'are impracticable, unnecessary, or contrary to the public interest'") (emphasis added).

[24] Under this approach, it would still be appropriate for CMS to forgo prior notice and comment rulemaking when it adopts both an updated standard that does not add new functions necessary for the transaction as well as the prior adopted standard with which the updated standard is "backward compatible." *See* 70 Fed. Reg. 6267. Under such circumstances, no new compliance burden would be established, because the prior adopted standard could still be used to comply with the e-prescribing regulations.

[25] *See, e.g.*, General Electric Co. v. EPA, 290 F.3d 377, 382-83 (D.C. Cir. 2002) ("If a document expresses a change in substantive law or policy . . . which the agency intends to make binding, or administers with binding effect, the agency . . . must observe the APA's legislative rulemaking process").

[26] *See* SSA § 1860D-4(e)(4)(C)(ii).

[27] We also note that, according to the Proposed Rule, it appears CMS will specify each e-prescribing standard (including version number and date of adoption) in the text of the regulations. *See* 70 Fed. Reg. 6273-74 (proposed 42 C.F.R. § 423.160(b), (c)). It does not appear that changes to this regulatory text to reflect the adoption of new versions of the standards (which CMS appropriately would establish via a legislative rule through notice and comment) could be made except by another legislative rule, such as an interim final rule or prior

Summary of Recommendations

The major recommendations made in these comments may be summarized as follows.

1. Consistently request a coherent set of design principles to develop system standards

   - Design the system to improve patient care and strengthen the physician-patient relationship by putting the patient first, protecting patient privacy, promoting physician-patient communication, and protecting the physician's role.
   - Provide information needed by prescribers (and information needed to protect beneficiaries) at the point of care. Ensure that the system can work with other electronic health information systems to obtain this information.
   - Reduce the overall cost of care and provide value to all parties using the system.
   - Cover the entire prescribing process.

2. Do not focus exclusively on information content. When appropriate, standards should also regulate the integrity and display of this information.

3. When assessing the system's value, consider its impact on all aspects of health care costs, and the extent to which it actually is accepted and used.

4. Retain and strengthen the current criteria for "adequate industry experience."

5. Drop the "Formulary Alternatives List" from the proposed NCPDP Formulary and Benefit Standard.

6. All steps in prior authorization should take place through the e-prescription system, at the point of care.

7. Drug information should match the structured product label (SPL) in content and format. Any additional information should satisfy the standards developed for e-prescription messages.

8. Standards for e-prescription messages should be developed before messages are allowed (even during pilot testing).

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notice and comment rulemaking. *See, e.g.*, Hemp, 333 F.3d at 1088 ("only legislative rules (*i.e.* rules having the force of law) can amend a prior legislative rule"); Erringer v. Thompson, 371 F.3d 625, 632 (9th Cir. 2004) ("Any rule that effectively amends a prior legislative rule is legislative and must be promulgated under notice and comment rulemaking").

9. Rely on SPL and formulary information, along with symbols indicating when AB-rated generics are available, to help prescribers to identify lower cost therapeutically appropriate alternatives.

10. Establish an infrastructure for the development process that enables all stakeholders to play a meaningful role.

    - Create and publicize a blueprint for the system.
    - Provide clear and consistent guidance.
    - Engage all stakeholders.
    - Promote pilot-testing.
    - Be proactive about identifying and resolving issues concerning other laws and requirements administered by CMS or HHS.

11. Adopt all final standards through formal rulemaking, including an opportunity for notice and comment. Updated versions of the final standards that do not impose a material new compliance burden may be adopted through an interim final rule with opportunity to comment.

We appreciate the work that will go into developing standards for the e-prescription system in response to the public's comments. We are confident that the resulting system will work well to achieve its objectives of improved access to affordable medicines. If you have any questions or we may be of further assistance, please feel free to call either of the undersigned at 202-835-3400.

Sincerely,

Richard I. Smith
Senior Vice President
Policy, Research &
Strategic Planning

Bruce Kuhlik
Senior Vice President
& General Counsel
Legal Department

Attachment

Appendix

Points from the Discussion of Commercial Messaging before and by the National Committee on Vital and Health Statistics (NCVHS)

From the NCVHS letter to the Secretary of Health and Human Services (HHS), September 2, 2004.

> **Observation 15 (Policies to Remove Barriers):** Testimony identified widespread industry concerns relating to safe harbor, preservation of provider/patient choice, and freedom from commercial bias in messages received through e-prescribing applications.
>
> Recommended Action 15.1: HHS should ensure that regulations define the parameters of safe harbor, ensure preservation of provider/patient choice, and require that e-prescribing messages received through e-prescribing applications be free from commercial bias.

From the Deliberations of the NCVHS Subcommittee on Standards and Security, July 29, 2004

- "In the testimony about level playing field, neutral presentation, you are going to put six drugs on a screen what is neutral to you? Is it alphabetical? I am serious. It is a good philosophy but give me a reality shot." *Harry Reynolds, BCBS North Carolina*
- "I sort of see [commercial messaging] as like a HIPAA issue, which is, it is part of regs. It is a complete driven process and if users are beginning to feel that there is too much commercial information coming down then it is something that CMS has to investigate." *Simon Cohn, MD, Kaiser (Subcommittee Chair)*
- "The concern about having commercial messages pop up (during) prescribing is not, in my mind, a standards issue. It is an issue related to the software application ... or the network vendor. That does not mean that I don't think it is important because from what we just heard, if we are blind to the effects of these, it not only hurts the different pharmaceutical companies that may try to be ethical, but it could be a deterrent to the acceptance of e-prescribing. ... We have a category here of important related issues and I think that is where this goes." *Jeff Blair, Medical Records Institute*
- "I think all of us want to make sure that e-prescribing promotes health but we also don't want to do marketing, which is I think what you were all pointing to, and so the question that always gets to me is that the line here is not a sharp

line and I think we saw that with the privacy regulations also and I am just reflecting on that." *Simon Cohn, MD, Kaiser (Subcommittee Chair)*

- (With regard to recommendations for a "zone of autonomy" around prescribers) "My question is, sort of, who and how those things would be enforced. Who should make those policies, what process would you recommend and then how would they be enforced because some of these I think at least they are essentially describing the content that would allow it to flow. It wouldn't really change the format of the standard or the technology standard. So, it is almost like now we have to have some sort of censor or policeman or somebody who is looking at content trying to decide whether these, I am having a hard time; I am struggling a little. I like the principles but I am struggling with the implementation and how this would work." *Stan Huff, MD, Intermountain Healthcare, University of Utah*

PhRMA

FAX

Policy and Research Division

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Date: 4/6/05

From:

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SENT PER MARIA FRIEDMAN'S INSTRUCTIONS. ORIGINAL COPY WAS DELIVERED TO HHS MAILROOM ON 4/4/05 BUT MAY HAVE BEEN MISDIRECTED.

PLEASE CALL WITH ANY QUESTIONS.

Number of pages including cover sheet 26

To: LAURA GANGE

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REMARKS:							
	☐	Urgent	☐	For your review	☐	Reply ASAP	☐	Please comment

Johnson & Johnson
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Michael Weinberger
Executive Director, Prescribing Alliances
Managed Markets Division

#6

April 5, 2005

Hand Delivery

The Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–0011-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-0011-P; Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Dr. McClellan:

On behalf of Johnson & Johnson Health Care Systems, I am writing to comment on the Proposed Rule entitled "Medicare Program; E-Prescribing and the Prescription Drug Program," see 70 Fed Reg. 6,256 (Feb. 4, 2005) (the Proposed Rule). Johnson & Johnson Health Care Systems Inc. provides account management and customer support services to key health care customers, including hospital systems and group purchasing organizations, leading health plans, pharmacy benefit managers, and government health care institutions. The company also provides contract management, logistics and supply chain functions for the major Johnson & Johnson franchises.

Johnson & Johnson Health Care Systems appreciates this opportunity to comment on this Proposed Rule and looks forward to working with CMS to ensure that e-prescribing is implemented in a manner that optimizes clinical standards of care and superior patient outcomes.

I. Johnson & Johnson Supports Electronic Prescribing

Johnson & Johnson Health Care Systems is a strong proponent of electronic prescribing. While proper studies are needed, we have every reason to believe that e-prescribing will result in fewer medication errors, improved process and cost efficiency, and better patient therapeutic compliance. We have also noted the observations made by many in the healthcare technology field that e-prescribing is a first step toward the broader adoption of electronic medical records and the electronic interchange of pertinent information between interoperable provider healthcare systems. While we support the principle of electronic prescribing, we want to ensure that, in moving quickly to realize its unique benefits, we do not inadvertently compromise a physician's ability to exercise his or her best clinical judgment to the detriment of patient care.

A. We Support CMS's Efforts to Identify and Evaluate Industry Experience with the Proposed Technical Standards; Standards for "Prescription-related Information" Should Not be Finalized without Adequate Pilot Testing

The Proposed Rule does an excellent job addressing the technical standards necessary to move prescription information "from Point A to Point B," and we support the agency's criteria for evaluating industry experience with these standards. Specifically, we agree that ANSI accreditation is an important indicator of industry experience. As noted in the Proposed Rule, the ANSI accreditation process is accessible to all interested stakeholders. See 70 Fed. Reg. at 6,261. Consequently, this process promotes broader industry participation and greater familiarity with these standards, which in turn increases the prospect that any final standards will address and be responsive to industry needs.

We also support the requirement that any e-prescribing standard must have been implemented by those entities that will be subject to the electronic prescribing requirements and should be recognized by key stakeholders as an industry standard. See id. Industry implementation is crucial to ensuring that any proposed standard will be capable of operating in the real world. Similarly, broad industry recognition is important to ensure that the standard is commercially viable, and not simply one of many "standards" currently in use that may not survive if the industry ultimately selects a single standard.

We agree with CMS that the industry has sufficient experience with the NCPDP SCRIPT and Telecommunication standards and the X12N 270/271 standard to warrant immediate adoption as foundation standards. We are not as confident about industry experience with those proposed elements of the technical standards regarding the transmittal of "prescription-related information" that is, formulary information, medical history, and medication history. Even if these can quickly become ANSI accredited, industry still lacks the same significant hands-on experience it has had with the other foundation standards. Therefore, as described below, we believe that these, and indeed all future standards, should be subject to (and not accepted as final without) the pilot testing provided for in the Medicare Modernization Act (MMA) and the Proposed Rule. See 42 U.S.C. § 1395w-104(e); 70 Fed. Reg. at 6,228, 6,261.

B. We Encourage CMS to Utilize the Pilot Testing Program to Assess Future E-prescribing Standards

Pilot testing of future e-prescribing standards, including formulary information, medical history, and medication history standards, is crucial to ensuring that they will function in a manner that enhances the prescribing process without placing an undue burden on users. For example, pilot testing will enable the agency to determine whether

standards that work in a closed system, among a relatively small number of stakeholders, remain effective in a larger, more open environment, or whether standards that operate flawlessly in isolation become problematic when combined with other standards. Pilot testing these standards is the only means for identifying and addressing these issues as they arise in a real-world environment. As a result, we believe that all future e-prescribing standards must be subjected to pilot testing to help ensure the program functions as Congress intended.

In addition to evaluating the real-world functionality of technical standards, pilot testing is also crucial to assessing certain concerns not addressed in the Proposed Rule, namely those process standards that are necessary to ensure that e-prescribing does not interfere with physician prescribing practices. In this regard, in the MMA and its accompanying Conference Report, Congress identified several areas of concern in the e-prescribing program, specifically prohibiting inappropriate messaging and indicating that physicians should have unbiased access to the full range of prescribing information. See 42 U.S.C. § 1395w-104(e)(3)(D); H.R. Conf. Rep. No. 108-391, at 455. Nevertheless, the Proposed Rule contains virtually no discussion of these issues. See, e.g., 70 Fed. Reg. at 6,262. These process standards are discussed in greater detail below.

II. Process Standards: Enhancing the Rule to Set Standards for the Operational Characteristics of the Interface in Addition to "Technical Standards"

As mentioned above, the Proposed Rule focuses on the technical standards needed to transmit information. However, we believe that the MMA contemplated, in addition to technical standards, governance of how software programs interact prescribers. On March 1, 2005 CMS held an Open Door Forum on electronic prescribing. At that meeting, several parties including Johnson & Johnson Health Care Systems, commented on the value of establishing not only standards for the technical transmission of prescription information but also "process standards."

Process standards are those standards that ensure fairness in the prescribing process used by an e-prescribing system. They apply to the actual act of electronic prescribing; the manner in which information is presented to prescribers and the way in which systems interact with those prescribers. The intent of Congress, as seen in the MMA and its accompanying Conference Report, is that e-prescribing standards would ensure that e-prescribing systems function in a fair, transparent, and unbiased manner. Specifically, the MMA requires that e-prescribing "allow for the messaging of information only if it relates to the appropriate prescribing of drugs," and the Conference Report states that prescribers must have access to "neutral and unbiased information on the full range of covered outpatient drugs." 42 U.S.C. § 3195w-104(e)(3)(D); H.R. Conf. Rep. No. 108-391, at 455-56. The Conference Report further states that Congress did not intend for e-prescribing "to be used as a marketing platform **or other mechanism to unduly influence the clinical decisions of physicians**." Id. (emphasis added).

It is this underlined passage that we believe indicates the need for CMS to implement process standards for the user interface. We are concerned that, absent such standards, the potential exists that this technological opportunity will be abused. Consequently, we believe that it is important that the regulations include safeguards to proscribe inappropriate messaging that is aimed at influencing the prescribing decision.

A. The Most Likely Location for Misuse: The User Interface

In particular, we believe that "neutral and unbiased" presentation covers not just the information itself, but the way in which the display of that information could be manipulated to drive particular behaviors. We believe that, when a physician prescribes a drug, he or she should be presented with all pertinent information at the beginning of the prescribing process, including a single, consolidated list of appropriate drugs. This list should indicate which drugs are on-formulary preferred, on-formulary but not preferred,

and entirely off-formulary. The listed information should be provided on a single (and if necessary scrollable) screen without the need for excessive "clicking" or burdensome navigation. Presenting this information in any other manner might constitute an attempt to unduly influence the physician's selection before he or she has been fully informed of the complete range of choices and may make it less likely that the physician will see the names of drugs that may offer better efficacy and tolerability for the patient, but are not as incentive- and rebate-friendly. We strongly believe that, under the best standard of care, a physician and patient should be given full exposure to all clinical and financial information related to a prescription prior to a therapeutic decision being made. The regulations should promulgate process standards that expressly incorporate these protections.

B. Inappropriate Messaging Should be Clearly Defined

As noted above, the MMA clearly proscribes inappropriate messaging. See 42 U.S.C. § 1395w-104(e)(3)(D). It is our position that such messaging must be understood to include not just commercial advertising, but any kind of messaging via the interface, the intent of which is to effect a change in the prescription without respect to clinical factors. We are not suggesting that physicians should not be made privy to financial information such as formulary status and cost to the patient. To the contrary, physicians clearly should have this information. However, they should receive such information up front, before making the prescribing decision. We believe that messages that are triggered by non-clinical aspects of the prescription could be used to make the prescribing experience burdensome or inconvenient until the physician ultimately submits to changing the prescription despite his or her clinical opinion on what is the best treatment for the patient. The agency should promulgate process standards that prohibit this inappropriate messaging.

C. Prohibiting Inappropriate Financial Incentives

We believe that in order to satisfy the clear intent of Congress that the prescribing process be unbiased and objective, the regulations should not permit plans, PBMs, or other entities to pay vendors engaged in the electronic prescribing process based on which drugs are prescribed. Thus, these entities should not be permitted to pay these vendors a "bounty" for each prescription they successfully switch from the physician's intended selection to a more rebate-friendly or otherwise financially appealing choice that does not specifically consider the best care of a particular patient. While, in some instances, the preferred formulary drug may achieve the best balance of clinical and financial value for the patient, in other cases, there may be drugs that are on-formulary but not preferred, or are off-formulary, which better serve the patient's needs. In these instances, the physician should not be subjected to interruptive pop-up messages that attempt to persuade him or her to select a certain drug because it is financially more attractive to certain stakeholders (e.g., due to higher rebates or incentive payments).

III. Conclusion

We appreciate the opportunity to comment on these important electronic prescribing issues raised by the Proposed Rule. We would be happy to provide additional information to you or your staff on the topics we have addressed in this letter.

Sincerely,

Michael Weinberger

#7

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

PCMA

April 5, 2005

The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File code CMS-0011-P

Dear Dr. McClellan:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the proposed rule to adopt standards for an electronic prescription drug program for the Medicare Part D program.

PCMA commends the Centers for Medicare & Medicaid Services (CMS) for recognizing that electronic prescribing provides the promise of improved patient safety, reduced health costs, and increased quality and efficiency of care for all Medicare beneficiaries. We also recognize the National Committee on Vital and Health Statistics (NCVHS) in developing the proposed standards in such a tight timeframe.

PCMA would like to summarize our position in the following points:

E-prescribing is key to patient safety.

- Of patients who received at least one prescription, 25% reported an adverse drug event and 39% of these events were preventable.
- Complete patient medication history made available through e-prescribing would help identify potential adverse drug interactions.
- E-prescribing avoids complications associated with illegible, hand-written prescriptions.

E-prescribing can result in huge cost savings.

- Access to formulary information (such as lower-cost generics and co-pay information) at the point of prescribing can ensure appropriate care while reducing expenditures.

PBMs are at the forefront of e-prescribing.

- An infrastructure that connects payers, physicians and pharmacies is key to the effective utilization of e-prescribing systems. PBMs already utilize such a system.

National uniform standards are necessary to make e-prescribing work.

- A patchwork of state standards will create barriers to adoption of e-prescribing by prescribers, pharmacists and payors in Medicare and the commercial sector.

In the 2004 eHealth initiative report titled "*Electronic Prescribing: Toward Maximum Value and Rapid Adoption*" it is stated that Americans made more then 823 million visits to physicians' offices in 2000 and, according to the National Association of Chain Drug Stores (NACDS), four out of five patients who visit a doctor leave with at least one prescription. More than 3 billion prescriptions are written, and prescription medications are used by 65 percent of the U.S. public in a given year. The study goes on to state that 25 percent of patients who received at least one prescription reported an adverse drug event, and 39 percent of these events were deemed either ameliorable or preventable.

Electronic prescribing can help prevent medication errors because it instantly links the health care provider, the pharmacy, and the payers. Patient medication history and insurance information can be available for the physician when prescribing and, at the pharmacy, each prescription can be checked electronically for dosage, interactions with other medications, and therapeutic duplication. Patient safety can also be improved through avoiding hard-to-read physician handwriting and by automating the process for determining drug interactions and allergies.

E-prescribing can also improve efficiency and reduce costs by providing information about the formulary, including lower cost generics, and co-pay information. It can help make sure that patients and health professionals have the best and latest medical information at hand when they make important decisions about medicines, helping patients get the most benefits at the lowest cost. In addition, e-prescribing shows promise in creating efficiencies in the physician's office and the pharmacy. This can be done by reducing the costs associated with patient eligibility checks and creating timely interfaces with formularies to make sure the correct drug is prescribed the first time.

State Preemption
[Background, A. Statutory Basis, H. Summary of Status of Standards for an Electronic Prescription Drug Program]

PCMA is concerned with the limited manner in which CMS has interpreted its preemption authority. We recommend that CMS revise the limited interpretation of preemption to ensure the federal standards fully preempt any state law or regulation that affects e-prescribing. We believe the clear intent of Congress was to limit the barriers of physician and pharmacist adoption of e-prescribing and provided CMS with the authority necessary to ensure a single national standard.

PCMA believes that creating unified e-prescribing standards through appropriate and full preemption of state laws is a critical component to the ultimate success of e-prescribing. State laws and regulations, if they deal with e-prescribing, tend to make the e-prescribing process less efficient, or even illegal, and therefore not likely to be utilized by payors, physicians and pharmacists. The National Association of Boards of Pharmacy (NABP) model act, states that electronic prescriptions must be transmitted directly to the pharmacy "with no intervening person or third party having access to the prescription drug order". For those states that have adopted this language, this would mean that electronic prescriptions that convey any formulary information or comprehensive medication history would not be allowed.

With the increased attention on the value information technology (IT) can provide the health care system, policymakers are becoming more familiar with the barriers that exist to broad health IT adoption. An often noted barrier to adoption is the possibility of numerous, disjointed standards that directly impact how these systems will work in the practice setting.

In fact, the Department of Health and Human Services (HHS) press release in announcing the release of this proposed rule stated, "The current lack of common standards is a barrier to the use of health information technology, including e-prescribing."[1] Also, in the HHS Goals for a Strategic Framework for Health IT adoption said "the government has made a commitment to using common standards and architecture…The result will be a more cost-effective and efficient healthcare system."[2]

The GAO has identified in its 2004 report, "HHS Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption," specific barriers to adopting Health IT include financial, technical, and cultural aspects. Technical barriers, including a "lack of uniform standards for data submission and reporting" clearly show that a uniform standard is critical for the federal government to reduce or eliminate as many barriers to adoption as possible.

Despite a consistent call for uniform standards, the preemption interpretation in the NPRM creates a system that enables numerous and differing standards which subsequently creates barriers to adoption by prescribers, pharmacists, and payors. Under the interpretation of preemption within the NPRM it is possible to have differing Medicare e-prescribing standards in each state, even if that state is combined in a single PDP or MA region

NPRM, p. 6258- Adopted Medicare standards must create a conflict for a state law to be preempted.

Comment- PCMA disagrees with this interpretation and recommends CMS reverse this interpretation.

It is of particular importance that under no circumstance should an individual state e-prescribing standard apply to the Medicare program even in situations where Medicare has not formally adopted a specific e-prescribing standard. There are aspects of e-prescribing contemplated in the statute that are beyond the traditional regulation of practicing pharmacy and directly relate to benefit and plan design where state pharmacy laws should not have jurisdiction.

The Medicare established e-prescribing standards should be adopted in a manner that does not require a standard-by-standard evaluation to determine which individual state standard may or may not be preempted. This would create a burdensome review to compare the Medicare

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[1] "E-prescribing proposed rule," Department of Health and Human Services-Press Release.

[2] "Goals of Strategic Framework." Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONCHIT);

e-prescribing standards and that of each relevant state law and regulation to determine where Medicare has created a standard and where it has not.

Preemption is also addressed in Sec. 1860-D-12(g), which CMS has interpreted to apply to all state laws "except licensure and solvency."

This limited interpretation of preemption would be contrary to the intent of two provisions in the statute by applying e-prescribing standards to Medicare (besides those established under Part D) and creating administrative burden on prescriber and pharmacist obligations.

First, the statute states in Sec. 1860D-4(e):

> "...prescriptions and other information described in paragraph (2)(A) for covered Part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2)." [underline added]
>
> In addition, the Conference Agreement also states:
>
> "The [e-prescribing] standards apply to prescriptions for covered part D drugs and required information that are transmitted electronically under an electronic prescription drug program conducted by a PDP or MA plan."[3]

While Congress did not require prescribers to use e-prescribing, this section demonstrates—1) the intent that any electronic prescribing that occurs in Medicare will follow the Medicare standards and 2) that these standards would apply to any e-prescribing program conducted by a PDP or MA plan. This would include any part of Medicare, including Part A, B, C or D.

Second, the statutory language at Sec. 1860D-4(e)(3)(C)(i) states:

> "standards be designed so that, to the extent practicable, they do not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists."

With the potential of having to determine which state standard or Medicare standard applies in a variety of known and unknown situations, prescribers and pharmacies will experience enormous burden to carry out Medicare e-prescribing. In fact, situations would exist that performing Medicare e-prescribing would actually violate state prescribing laws.

NPRM, p.6258-6259- Preemption is limited only to the Part D program.

Comment- PCMA disagrees and recommends CMS interpret preemption to apply broadly to state laws and regulations beyond Medicare.

---

[3] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Conference Agreement. p.23

We believe CMS has the authority necessary to govern all electronic prescription of any drugs included in the Part D program, so as to ensure a single, national electronic prescription drug program that would be adopted and used consistently by prescribers to the benefit of Medicare and the rest of the health care system.

Examples of state e-prescribing laws or regulations that are burdensome include: requiring a fax or hard copy to follow an e-prescription, prohibiting specific scheduled drugs, and prohibiting interstate transmission of prescriptions.

With a large focus of resources and time needed by all partners in the e-prescribing systems to overcome the obvious challenges of prescriber start up costs and broad education about the value proposition of e-prescribing, it is critical that the standards and processes that make the technology function not add to this formidable challenge.

Stark Anti-kickback
[A. Statutory Basis, 3.Anti-kickback Safe Harbor and Stark Exception]

Comment:

We look forward to reviewing and commenting on the impending OIG NPRM relating to this safe harbor. PCMA believes it is critical that incentives be allowed to be offered to providers by PDPs, PBMs, and health plans to encourage provider adoption of e-prescribing.

Foundation standards
[F. Evolution and Implementation of an Electronic Prescription Drug Program]

Formulary and Medication History Information

Comment:

PCMA recommends that the Rx HUB standards for formulary and benefit information be considered to have sufficient industry experience and therefore included as foundation standards. We do not believe it is necessary for ANSI accreditation to demonstrate sufficient industry experience. For a meaningful e-prescribing system, it is critical that formulary information and medication history be included as soon as practical. These two functions provide the backbone for the ultimate goals of e-prescribing—increasing patient safety and reducing cost.

While there is value in the ANSI accreditation process, CMS should not require ANSI accreditation of e-prescribing standards to be included as foundation standards. The Rx HUB standards are in operation today by the three largest pharmacy benefit managers (PBMs) and no other alternative exists today. In addition, the possibility exists that the ANSI accreditation process would be slowed down by those who may not favor expedient adoption with no alternative approach.

ASC X12N 270/271

Comment:

We support the naming of the ASC X12N 270/271 transaction set as a "foundation standard" for the MMA e-prescribing program. The ASC X12N 270/271 is currently in widespread use for checking eligibility and is used in a manner compliant with the HIPAA privacy regulations between prescriber and pharmacy benefit managers/payers.

We understand that there is not much (if any) industry experience in using the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the dispenser to the payor. In addition, the E1 message is not designed to handle multiple coverage (COB) responses, as it is only designed to handle verification of a patient's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not being used, we recommend that it be excluded from the final rule. At minimum, we recommend that this transaction be piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

National Provider Identifier (NPI)

Comment:

PCMA supports the goal of having a single system for identifying providers and the long term solution of using the identifier for all transactions that require one. However, the current timeframe for implementing the NPI should not be altered, and any temporary solution should look to current industry practice until the NPI is fully implemented.

CMS should make use of identifiers that are currently available and in use such as the NCPDP Provider Indentifier Number. This identifier should be adopted for electronic prescribing until the NPI is fully in place. Any other approach will create significant inefficiencies by forcing the industry to change processes and adapt something new, only to make additional changes when the NPI is implemented a short time after.

PCMA is committed to continue working with HHS, CMS and all relevant stakeholders to realize a national e-prescribing solution that will improve patient safety, limit administrative burdens on prescribers, and reduce costs for the Medicare program as well as the commercial sector.

Sincerely,

Mark Merritt

#8

American Academy of Dermatology Association

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April 5, 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

RE: Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

Dear Dr. McClellan:

On behalf of the 14,000 members of the American Academy of Dermatology Association, I appreciate this opportunity to comment on the proposed rule for electronic prescribing (e-prescribing) standards. These standards represent another important step on the road to developing, promoting, and integrating a national health information technology network for healthcare professionals to provide safe, quality-based, efficient and affordable patient care.

As office-based physicians, dermatologists recognize e-prescribing is as much a patient safety issue as it is a workflow issue. Indeed, the most apparent benefits for dermatologists using e-prescribing include: speedy point-to-point ordering, transmission and tracking from physician prescribers to dispensing pharmacies; reduced medication errors or duplication; increased accuracy and transparency of the transaction; improved legibility; efficiency gains in practice workflow and reduced administrative steps; as well as enhanced ability to share and coordinate patient care information.

To achieve and maintain these benefits we feel that the proposed federal e-prescribing standards should allow for the operational flexibility and scalability for the prescribing physicians. This would facilitate appropriate management of prescription volume and medication options, especially in ambulatory practices. Furthermore, we urge that the initial e-prescribing standards adopted for the 2006 test pilot project be designed to include the full participation of office-based specialists, including dermatologists, in both rural and urban settings in order to identify and mitigate against any potential health information technology divide and socio-economic disparity that may compromise the quality, safety, and efficiency in the delivery of patient care. Effectively, the results from proposed e-prescribing pilot testing should help address the need for physicians in small and medium-sized ambulatory practices to adopt uniform, user-friendly, and interoperable standards for the provision of safe, quality-based care.

The proposed federal standards should take into account, and promote the elimination of, prevailing barriers to adoption and usage most common among small and medium-size dermatology practices. These barriers include:

- Cost of purchasing and implementing such a system;
- Lack of interoperable capabilities between healthcare professionals to ensure effective coordination of care;
- Complex and user-unfriendly health information technology that offsets any benefits related to administering quality of care;
- Lack of reliable systems' interface with existing practice systems; and
- Lack of financial incentives for the small business provider;

These significant disincentives need to be addressed and these current obstacles removed in order to promote adoption and implementation by physicians.

The Academy is confident that e-prescribing can help advance safe, quality-based, efficient and affordable patient care; therefore further consideration must be given to overcoming the above structural, operational and fiscal barriers. Healthcare electronic processes can be beneficial for both patients and physicians and e-prescribing is another step in the right direction.

Thank you for reviewing these comments. If you have any questions regarding our recommendations, please contact Jayna Bonfini at jbonfini@aad.org at 202-712-2614, or William Brady at wbrady@aad.org or 847-240-1824.

Sincerely,

Brett Coldiron, MD, FACP
Chair/AAD Health Care Finance Committee

Cc: Clay J. Cockerell, MD, President, AADA
Stephen P. Stone, MD, President-Elect, AADA
David M. Pariser, MD, Secretary-Treasurer, AADA
Ronald A. Henrichs, CAE, Executive Director and CEO, AADA
John D. Barnes, Deputy Executive Director, AADA
Judith Magel, Director, Health Policy and Practice, AADA
Laura Saul Edwards, Director, Federal Affairs, AADA
Cyndi Del Boccio, Director, Executive Office, AADA
Norma Border, Senior Manager, Coding and Reimbursement, AADA
Jayna Bonfini, Manager, Political Affairs, AADA
William Brady, Manager, Practice Management, AADA

Rec'd by TFM

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#9

ACP

AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

April 1, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on the Medicare Program: E-Prescribing and the Prescription Drug Program Proposed Rule (42 CFR 423).

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 116,000 doctors of internal medicine and medical students, is pleased to submit comments on proposed rule 42 CFR 423 --- "Medicare Program: E-prescribing and the Prescription Drug Program." ACP is well aware of the outstanding potential of e-prescribing to benefit the health of Medicare beneficiaries, and ultimately all Americans, in terms of reduced medication errors, improved quality of care, enhanced administrative efficiencies and lower costs. We are requesting your attention to the following issues to help ensure effective implementation of e-prescribing within the Medicare program.

1. The proposed prescription and eligibility/benefit electronic communication "foundation" standards.

The ACP supports your proposed implementation as "foundation" standards the NCPDP SCRIPT standard for prescription communications, the ASC X12N 270/271 Transaction standard for eligibility transactions between providers/institutions and health plans or just between health plans, and the NCPDP Telecommunication Standard for conducting eligibility transactions between dispensers and Part D sponsors. Each of these standards is already in widespread use in the industry both as individual standards and in combination and are recognized by the primary stakeholders within the e-prescribing field.

2. The inclusion of formulary representation and medication history standards in the final rule.

The proposed rule states the Centers for Medicare and Medicaid Services' (CMS') intention to adopt, as foundation standards in the final rule, formulary representation and

medication history standards, if certain characteristics are met and there is adequate industry experience with the standards. While we support the defined decision criteria, we strongly recommend the additional criterion of evidence that the standard successfully interacts with the other foundation standards. It is our opinion that such evidence is lacking and that pilot testing is necessary to ensure the usefulness and correctness of the standard.

3. The need to facilitate the rapid development of RxNorm and SPL structured terminology.

The College encourages CMS to expedite the development, pilot testing and implementation of the RxNorm terminology and SPL document specification. This common dictionary and structure will allow for the e-pescribing system to adequately capture subscriber intent when bridging systems using disparate drug databases. In addition, it would allow for the addition of multiple clinical decision support features into the system that have the potential to reduce medical errors and improve quality of care.

4. The proposed rule would require most hospitals and other large clinical settings to change their current prescription transmission standard.

HL 7 is the prescription transmission standard currently used by a predominance of hospitals and other large care delivery organizations. These facilities often require the complex/detailed prescription messages available with HL7, and not currently available through the NCPDP Script standard. These facilities would have to develop and support, at some substantial expense, NCPDP Script standard for prescriptions ordered under the Medicare Part D program under the current proposed rule. The College recommends that CMS address this issue and explore the possibility of changes to the proposed rule that would allow both HL7 and NCPDP Script specifications for prescription transactions. For example, the proposed rule could be modified to support the use of an intermediary that may be a different enterprise than the prescriber in translating HL7 pharmacy order messages to the required NCPDP format. The Cleveland Clinic Foundation has already demonstrated the feasibility of this approach.

ACP also requests that CMS address the more general issue of harmonizing e-prescribing communications between the hospital and outpatient settings. For example, a medication list provided by an outpatient setting should be able to inform the admission inpatient orders; and the inpatient order list should inform the outpatient medication list at the time of discharge.

5. The use of the HIPAA electronic transmission definition to define providers covered by the proposed rule will add inefficiencies and a significant financial burden to most providers employing electronic health record (EHR) systems.

Currently, most providers using an EHR system electronically fax prescriptions to patients' pharmacists. These providers would fall under the proposed e-prescribing rule based upon the HIPAA electronic transmission definition, which includes medical

8. The issue of unique identifiers for dispensers, providers and patients.

ACP strongly supports the recommendation of the National Committee on Vital and Health Statistics (NCVHS), and the Department of Health and Human Services' (HHS') proposed intention of requiring the National Provider Identifier (NPI) for all dispensers and providers participating in the electronic prescription program under Medicare Part D. The College also urges HHS to accelerate the enumeration of all providers and dispensers to support transition to the NPI for e-prescribing by the onset of the Part D program on January 1, 2006.

The proposed rule does not address the issue of a unique patient identifier. ACP believes that there are patient safety benefits in the use of a unique patient identifier in terms of ensuring accurate matching of prescription and patient data that far outweighs any reasonable privacy or government intrusion concerns. The College recommends that HHS use its resources to place this issue "on the table" for further discussion.

9. The issue of how the e-prescribing system will address "dispense as written" and "brand name medically necessary" instructions.

ACP requests that HHS define their plans for addressing "dispense as written" and "brand name medically necessary" prescription instructions within the federal e-prescribing program.

10. The enactment, monitoring and enforcement of regulations under the Medicare Part D e-prescribing system that ensure that prescribing health care professionals have ready access to neutral and unbiased information on the full range of covered drugs.

Both language in the MMA (1860D-4(e)(3)(D)) and the legislation's conference report reflect Congress' intent of ensuring that prescribing health care professionals have ready access to neutral and unbiased information on the full range of covered drugs under the Medicare Part D e-prescribing system. ACP is concerned that the proposed rule does not address this issue.

The College recommends that HHS enact regulations, and the means to monitor and enforce them, that prohibit the transmission of commercial messages within the Medicare Part D e-prescribing system that will unduly bias physician's drug selection. In addition, the College recommends that HHS provide similar protection to ensure that health care prescribers have neutral and unbiased access to information on <u>all</u> covered drugs available in a plan's formulary.

11. The need for incentives to promote provider adoption of electronic prescribing.

ACP believes that e-prescribing, along with electronic health records, has the potential to significantly improve patient safety and quality of care. Unfortunately, recent testimony presented before the NCVHS estimates that only between 5-18 percent of prescribers are

currently conducting e-prescribing. A primary barrier to physician adoption is the cost of buying and implementing these systems, making related changes in the flow of office practices and training staff. ACP recommends the following incentives --- particularly in the smaller physician practices that treat a large number of our Medicare beneficiaries --- to support the significant 10 percent annual expansion of e-prescribing over the next 5 years projected in the proposed rule:

- The availability of financial incentives (e.g. grants, loans, tax incentives) and payment increases contingent on the use of this technology to promote the initial implementation and maintained use of e-prescribing technology. These financial incentives are particularly important in small, rural and underserved clinical settings.
- The expedited revision of the Stark laws and the development of Medicare Anti-kickback law safe harbors (with strong state preemptions) to allow health plans and others, who stand to most benefit financially from adoption, to provide necessary hardware/software, technical assistance and financial incentives to providers.

In addition, there is need for increased discussion and the collection of data on how implementation of e-prescribing may affect physician personal liability risk and related insurance coverage. HHS's has suggested that implementation may decrease medical liability premiums due to its effect of decreasing medication errors. On the other hand, some clinicians have expressed concern about the potential of increased liability risk due to the making of medication judgments based on information (which may or may not be accurate) provided through the e-prescribing system. Furthermore, situations in which physicians choose, based on clinical judgment, to over-ride adverse reaction alerts or other clinical support information ultimately provided by the e-prescribing system also have the potential to increase liability risk This issue clearly requires further exploration and the collection of relevant data.

12. The following issues were not discussed in the proposed rule and need to be addressed in future pilot studies related to the federal e-prescribing system:

- The need for all new standards added to the foundation standards (and other standards ultimately included into the system) to have adequate documentation of successful interaction to ensure the usefulness and correctness of the standard package.
- The need for means of communicating patient choice of pharmacy and change of pharmacy instructions. Optimally, the e-prescribing software should provide more than one pharmacy choice for the patient. In addition, patients who choose to change pharmacies should easily be able to have their prescriptions transferred from one pharmacy to another.
- The need for a "no fill" message to be sent to the prescribing provider.
- The need for performance and notification/acknowledgement of transmissions standards among all parties in the e-prescribing relationship.

- The assessment of the error rate in electronically transmitted prescriptions with the goal of achieving an error rate at least as low as that currently found in the banking industry --- which approaches zero.
- The evaluation of the e-prescribing process to target specific obstacles to adoption in multiple clinic; urban and rural; and small and large practice settings. These evaluations should address financial, staffing and practice flow components of the process.

The ACP appreciates this opportunity to comment on the proposed e-prescribing standards. Please do not hesitate to contact Neil Kirschner on the ACP staff at 202 261-4535 and nkirschner@acponline.org if you have any questions regarding the submitted comments.

Sincerely,

Joseph W. Stubbs MD

Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

Recd by TFM

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#10

Bonnie Washington
Vice President Health Policy

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April 5, 2005

BY HAND DELIVERY

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments on Notice Proposed Rulemaking: Medicare Program; Electronic Prescribing and the Prescription Drug Program [CMS-0011-P]

Dear Dr. McClellan:

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I am pleased to provide you with Novartis' comments on the first proposed rule on standards for an electronic prescription drug program as required by the Medicare Modernization Act of 2003 (MMA). Novartis Pharmaceuticals is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health.

We understand that this proposed rule is the first of several documents that CMS will be putting forth in its establishment of an electronic prescription program for the Medicare drug benefit, and the comments that follow focus on CMS' general approach and focus as it moves forward with e-prescribing. We commend CMS for it efforts on electronic prescribing thus far, including CMS' recognition that safety and quality are of utmost importance. We also recognize CMS' efforts to initially move forward in finalizing only those standards that have broad support and adequate industry experience and we hope that CMS continues to move in such a prudent manner in the future.

If you have any questions or require clarification on any of our comments, please do not hesitate to contact me.

Sincerely,

Bonnie Washington

Bonnie Washington
Vice President, Health Policy
Novartis Pharmaceuticals Corporation
202-662-4378

NOVARTIS

NOVARTIS PHARMACEUTICALS CORPORATION
COMMENTS ON CMS PROPOSED RULE (CMS-0011-P)

COMMENTS TO "BACKGROUND" – CMS-0011-P

Recommendation: CMS should ensure that patient safety and quality remain the first priority in implementing e-prescribing and that the physician's role is protected.

Comments: Novartis commends CMS for its commitment to improving patient safety, promoting quality of care, and reducing medical errors. We also recognize the potential value e-prescribing holds for all stakeholders in the health care system. Although utilization of e-prescribing technology is growing, it is clear that its use is far from widespread and that there are many unknowns regarding its impact on providers and patients, particularly older Americans.

We urge CMS, in coordination with the Agency for Healthcare Research and Quality (AHRQ), to evaluate the impact and utilization of e-prescribing during both pilot testing and once the e-prescription standards are finalized, and to widely disseminate information on its impact on patients and overall value.

We recognize that e-prescribing will be an important tool to improve safety and quality in the Medicare program and believe strongly that e-prescribing should also support the clinical judgment of physicians. Therefore, any incentives utilized in such a program should support the physician's role in the care process and appropriately reward physicians for improvements to safety and quality. Incentive payments based solely on physician cost containment disregard the primary goals and value of e-prescribing and the legislators' intent.

Recommendation: An e-prescribing system should provide key information at the point of care.

Comments: An e-prescribing system should provide physicians with the information needed to discuss drug therapy with the patient at the point of care. E-prescribing should facilitate these types of processes, including allowing physicians to efficiently determine the most appropriate drugs and course of treatment available for particular beneficiaries through mechanisms such as electronic prior authorization. Simplicity will be a significant factor in determining whether prescribers embrace e-prescribing, and the value of an e-prescription system will be compromised if prescribers do not have immediate access to the necessary information and are forced to use alternative systems that are slower, more complicated, or simply unavailable at the point of care. Additionally, an e-prescribing system should alert prescribers to provide beneficiaries with immediate notification of their right to request an exception or appeal and the information required to do so.

NOVARTIS PHARMACEUTICALS CORPORATION
COMMENTS ON CMS PROPOSED RULE (CMS-0011-P)

Recommendation : CMS standards for the e-prescribing user interface should promote physician treatment options.

Comments: The standards CMS adopts for formulary and benefit coverage information should provide beneficiaries with easy access to the comprehensive list of available drugs.

CMS and the National Committee on Vital and Health Statistics (NCVHS) should continue to work together with key stakeholders to develop relevant and appropriate standards to ensure that under the e-prescribing program, physicians have easy access to the comprehensive list of available drugs. Such information should be presented in a single, neutral, and comprehensive manner (for example, listed alphabetically). Additionally, the user interface must not create any barriers for physicians to prescribe medications that, for example, are on the formulary but are in a higher cost-sharing tier if the physician decides that the drug on the higher tier is medically necessary. Appropriate display of such information is necessary to ensure that the prescriber easily understands the full range of prescribing options available for the patient, and is not inappropriately influenced, and that the display does not impede decision making or place a burden on those using the system.

Recommendation: E-prescribing standards should reflect the MMA's prohibition on commercial messaging and CMS should work to provide more detailed guidance on this issue.

Comments: The law specifically prohibits the use of inappropriate messaging such as marketing or commercial messages. We strongly urge CMS to work with NCVHS to investigate this issue in more detail, including gathering input from all stakeholders, with the goal of providing clear guidance to plans on the types of messages that are/are not appropriate.

Different types of standards related to messaging may be required. For example, messages that appear before the prescriber begins the decision making process may be less likely to convey specific or appropriate information used in the prescribing process and more likely to contain advertising. Messages sent to the prescriber after a prescription has been transmitted may be problematic if they are intended to pressure the prescriber to change an earlier prescribing decision rather than to correct a prescribing error. Given this, we urge CMS consider any such messages to be plan marketing material and to review these messages as such during any CMS review of a plan's marketing materials.

Messages related to therapeutic alternatives also raise a range of issues. For example, what claims will be made about purported alternatives, and what qualifications or disclaimers will be included? Because such communications will consist largely of subjective judgements, the integrity of such information is of concern. Developing and testing standards in this area will require a significant amount of time because of such complexities, and adoption of standards in this area should be delayed until there is adequate industry consultation and pilot testing in this area.

Until CMS specifies more detailed guidelines, we urge CMS to send a strong signal to plans that it takes this issue very seriously, particularly given the MMA's intent. CMS should state that it will be watching developments in the commercial sector and working with NCVHS to produce appropriate guidance to ensure that e-prescribing does not provide an avenue for inappropriate interference in treatment decisions.

Recommendation: CMS should reject any incentives that raise Stark and Anti-kickback compliance issues.

Comments: We understand that CMS will propose a new Stark exception in separate rulemaking in the near future and that the Office of the Inspector General (OIG) will propose a new safe harbor under the anti-kickback statute, to cover certain nonmonetary remuneration relating to e-prescribing. Under the MMA, such remuneration could include "hardware, software, or information technology and training services...." We look forward to future guidance from both CMS and the OIG on these issues and the additional opportunities that will be afforded to comment.

We note in this regard that there is an important distinction to be made between monetary and nonmonetary compensation with regard to e-prescribing. Section 423.159(d) of CMS' final rule on the Part D drug benefit authorizes an MA-PD plan (but *not* a PDP) to provide a separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with the Part D program's e-prescribing standards. This regulatory provision, based on section 102(b) of the MMA, is intended to promote e-prescribing by MA plans. The MMA provides that the differential payment may take into consideration a physician's costs in implementing an e-prescription program and may be increased for physicians who significantly increase: (i) formulary compliance; (ii) therapeutic substitution; (iii) avoidance of adverse drug interactions; and (iv) efficiencies by reducing administrative costs. The MMA also provides that additional or increased payments for e-prescribing may be structured in the same manner as a PDP sponsor's medication therapy management fees to pharmacists under section 1860D-4(c)(2)(E) of the Act.

It is important to note that the future e-prescribing safe harbors to the Stark and anti-kickback statutes will be limited to the provision of nonmonetary remuneration, as defined above. Among other things, such protection would extend to support provided by a PDP sponsor or MA organization to network pharmacists, pharmacies, and prescribing health care professionals. This legislative provision for fraud and abuse protection of IT support does not, however, extend to an MA-PD plan's direct *monetary* payments to physicians to promote e-prescribing programs. Such payments are also distinguishable from medication therapy management fees because the remuneration goes directly to prescribing physicians rather than to dispensing pharmacies.

NOVARTIS PHARMACEUTICALS CORPORATION
COMMENTS ON CMS PROPOSED RULE (CMS-0011-P)

We concur with CMS's evident concern (as reflected in its preliminary solicitation of public comment on the issue) that an MA-PD plan's differential/increased payments to a physician who e-prescribes can raise substantial fraud and abuse issues. Given the nature of the proposed payments to prescribing physicians and the broad implementation latitude afforded MA-PDs choosing to pay physicians for e-prescriptions, serious fraud and abuse concerns could arise under both the Stark law and the anti-kickback statute, as described below.

A. Stark Law Compliance Issues

A serious Stark law compliance issue would arise if an MA-PD plan with its own in-house and/or mail order pharmacy were to make a direct payment to a prescribing physician under the e-prescription program. The final Stark II (Phase II) regulations indicate that CMS will expand the definition of "outpatient prescription drugs" (i.e., one of the designated health services ("DHS") to which the Stark law applies) to include covered Part D drugs provided for in the MMA, in addition to drugs covered under Medicare Part B. 69 Fed. Reg. 16,054, 16,104 (2004). An MA-PD plan with its own pharmacy therefore would become a DHS provider with a direct financial relationship (i.e., a compensation arrangement including, among other things, the differential payment for e-prescribing) with a referring physician. That relationship would trigger application of the Stark law. For the reasons outlined below, we do not believe the differential payment arrangements would be protected by any of the Stark law's exceptions. Therefore, referrals to the MA plan's pharmacy by a physician receiving differential or increased payments would violate the Stark law. In turn, submission of drug claims to Medicare resulting from those referrals would also be prohibited.

The Stark law includes a general exception, protecting both ownership and compensation arrangements with referring physicians, for services provided by certain types of prepaid plans to their enrollees. 42 U.S.C. § 1395nn(b)(3). Prepaid plans generally include those with Medicare risk contracts, such as MA plans. The Stark law's implementing regulations, however, provide further guidance on the scope of this exception, and it is the regulations that call into serious question the applicability of the exception to an MA-PD plan's differential payments to a referring physician for e-prescribing drugs for plan enrollees. The regulation describing the scope of protection for prepaid plans provides, in pertinent part, as follows:

> Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans [including HMOs and CMPs contracting with CMS under section 1876 of the Act] **(not including services provided to enrollees in any other plan or line of business offered or administered by the same organization)**....

42 C.F.R § 411.355(c) (emphasis added).

We believe that the bolded parenthetical would operate to make this Stark exception inapplicable. Medicare Part D payments to an MA plan are separate and distinct from the program's capitated payment to the plan for the standard Medicare benefits it provides under its risk contract. Although the Part D payment for the voluntary prescription drug program will include a risk-adjusted, capitated component calculated separately for MD-PD plan enrollees, it also will include cost-based payment components in connection with low-income subsidies, the catastrophic drug benefit, and risk-corridor adjustments. In short, the MA-PD plan design and payment system is clearly distinct from the MA capitated payment plan for standard Medicare benefits. Accordingly, the MA-PD operation constitutes a distinct plan operating, in essence, a separate line of business for the MA entity, taking it outside the scope of protection for prepaid plans defined in the regulation set forth above.

Nor do we believe that an MA-PD plan's differential payment to e-prescribing physicians would qualify for other Stark law exceptions for compensation arrangements. For example, the "fair market value exception" protects certain payment arrangements between an entity and a referring physician "for the provision of items or services by the physician..." when the payments are set in advance at a fair market value ("FMV") rate not taking into account the volume or value of referrals, and when other requirements are satisfied. 42 C.F.R. § 411.357(l). Under the e-prescribing program, the physician will be paid for simply writing a prescription electronically rather than in the traditional paper-based method. It is doubtful that merely writing a prescription would qualify as a separate "service" for which a physician could appropriately be compensated under this exception. The issuance of a prescription is an integral part of a patient's office visit or other medical evaluation or treatment service for which a physician arguably already is compensated under the Medicare physician fee schedule. In the Preamble to the Stark II (Phase II) regulations, CMS firmly resisted commenters' suggestions that it should expand the fair market value exception's scope of protection to remunerative relationships beyond the provision of "items and services." 69 Fed. Reg. at 16,111. Moreover, because this exception requires payment to be at an FMV rate, the differential payment for writing an electronic script would duplicate the Medicare payment already made for the beneficiary's physician visit. It would be impossible to assign a separate FMV rate for merely writing the prescription. Accordingly, the MA-PD plan's differential and increased payment to referring physicians for e-prescribing would fail to qualify for the Stark law's fair market value or similar compensation arrangement exceptions.[1] We must therefore conclude that this Stark law compliance failure would prevent the lawful implementation of this aspect of the e-prescribing program described in the proposed regulations.

[1] Similar problems would exist with the Stark regulations' exceptions for personal service arrangements (42 C.F.R. § 411.357(d)) and bona fide employment relationships (42 C.F.R. § 411.357(c)).

B. Anti-Kickback Statute Compliance Issues

Although the proposed rule's differential payment provisions seek to induce physicians to use electronic prescriptions rather than handwritten ones, Novartis believes the broad discretion afforded MA-PD plans in structuring these payments could well produce the unintended consequence of generating payments to prescribing physicians that violate the anti-kickback statute. Further, no safe harbor protection would be available to protect these payments under either existing regulations or those to be developed under the MMA for nonmonetary remuneration in connection with IT support and the like. We summarize below our concerns about potential non-compliance with the anti-kickback statute.

The anti-kickback statute has been interpreted to prohibit any arrangement where one purpose of the remuneration is for the referral of Medicare- or Medicaid-covered services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Given an MA-PD plan's broad discretion under the proposed regulations to structure differential payments to e-prescribing physicians, there is nothing to prevent a plan from paying a higher differential payment when a Medicare beneficiary has a Part D prescription filled at the MA-PD plan's own in-house or mail order pharmacy. In our view, such a payment structure would clearly constitute an inducement to the physician to use the plan's own pharmacy for a Medicare-covered prescription drug in violation of the anti-kickback statute.

Finally, the OIG issued a Special Fraud Alert in 1994 addressing anti-kickback issues related to prescription drug marketing practices. The OIG raised serious anti-kickback statute concerns in connection with payments to prescribing physicians that can interfere with a physician's judgment in determining the most appropriate treatment for a patient. We respectfully submit that the proposed differential payments to e-prescribing physicians raise the same serious concern and ought to be reconsidered.

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April 5, 2005

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Attn: CMS-0011-P

Re: Comments On Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P

Dear Dr. McClellan:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule *Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P.* AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical LTC. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L.108-173, signed into law on December 8, 2004, took a giant step forward in providing increased benefits to Medicare beneficiaries in the critical area of prescription drugs. The legislation established a new voluntary prescription drug benefit under a new Part D of the Medicare program which is to be effective January 1, 2006. The new Medicare Part D will provide many benefits and also many challenges.

AHCA was pleased to submit comments on the proposed Part D rule implementing the MMA,[1] particularly in areas directly affecting LTC residents and LTC facilities.[2] We were gratified at CMS' responsiveness to our concerns in the Part D final rule[3] and in the guidance that CMS issued on March 12 regarding performance and service criteria for network LTC pharmacies (NLTCPS) and requirements for Part D Plan sponsors for a process for coverage transitions. There is still work to be done and many issues to be addressed, but we believe that CMS has made great progress. We value being part of the mutual effort of the government and the private sector to help Part D achieve its full potential of achieving better lives for our citizens, and in particular the lives of residents in LTC, and in continuing to improve the quality of their care.

The MMA also required that prescriptions and certain other information for covered drugs that are transmitted electronically must comply with final uniform standards promulgated no later than 2008 by the Secretary. These standards must meet MMA's requirements, as well as be compatible with other standards, including standards adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In the final Part D rule published on January 28, 2005, CMS requires Medicare Part D Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans, and other Part D sponsors to support and comply with electronic prescribing standards once final standards are in effect, including any standards that are in effect before the drug benefit begins in 2006. On February 4, 2005, CMS published the proposed rule providing the first set of uniform final standards for electronic prescribing (e-prescribing) under Part D for which we are now providing comments.

The Importance of E-Prescribing in the LTC Environment

The use of the standards is mandatory solely for Part D sponsors and even then only to receive or reply to e-prescribing transactions initiated by other entities. Providers that prescribe or dispense Part D drugs are required to comply with the standards only when they electronically transmit prescription information or certain other related information.

CMS indicates that while 75 percent of the 57, 208 pharmacies in the United States already have e-prescribing capability, only between 5 and 18 percent of physicians and other clinicians are e-prescribing. Except for certain exceptional initiatives,

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[1] *Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule*, 69 Federal Register *46632*, August 3, 2004.

[2] We use the term LTC facilities to refer to nursing facilities and intermediate care facilities for the mentally retarded (ICFs/MR). CMS expanded the definition of the term "long term care" facilities in 42 CFR 423.100 of the Part D final rule to encompass ICFs/MR.

[3] *Medicare Program; Medicare Prescription Drug Benefit, Final Rule*, 70 Federal Register 4193, January 28, 2005.

AHCA assumes that few if any physicians are e-prescribing with respect to residents of LTC facilities. This picture must change. The benefits of e-prescribing for patients are enormous. CMS articulates just some of the potential benefits as follows:

- E-prescribing can help prevent medication errors because, at the time of prescribing, each prescription can be checked electronically for dosage, interactions with other medications, and therapeutic duplication.
- E-prescribing can also improve quality, efficiency, and reduce costs, by:
    - Improving patient safety and quality of care through immediate access to medication history information, and the prevention of adverse drug events;
    - Providing information about formulary-based drug coverage, including formulary alternatives and co-pay information;
    - Speeding up the process of renewing medications; and
    - Providing instant connectivity between the health care provider, the LTC pharmacy, health plans/PBMs, and other entities, improving the speed and accuracy of prescription dispensing, pharmacy callbacks, renewal requests, eligibility checks, and medication history.
- E-prescribing also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, CMS also believes that many elements of the Medicare prescription drug benefit, including quality assurance, better information on drug costs (for example, through generic substitution), and medication therapy management (which is designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions) will be enhanced by e-prescribing.

CMS believes that these improvements, enabled by e-prescribing programs, will occur through, among other things, improved prescription drug-related quality and disease management efforts, and ongoing improvements in information systems used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. CMS also believes that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescription program provisions of the MMA are implemented.

It is clear that all these benefits and enhancements to quality of pharmacy care, deriving in great part from advancements such as e-prescribing, must be provided to LTC residents as well as Part D beneficiaries who do not reside in LTC facilities. They will constitute an advancement in -- and become a fundamental and integral

part of -- the quality of care in LTC facilities. Nationally, there are 1.6 million nursing home residents; this is a major group taking multiple medications and each medication requiring multiple nurse/physician communications (phone and fax) on a regular basis.

The benefits of e-prescribing that CMS articulates could assist LTC facility compliance with Medicare and Medicaid requirements of participation. For example, the survey guidance for requirements governing medication errors and unnecessary drugs is currently undergoing major revision under CMS contract to the American Institutes for Research (AIR). The AIR product is intended to provide specific information to assist surveyors in making appropriate determinations and severity assessment of noncompliance cited under the related regulations. It is inconsistent for CMS on the one hand to "beef up" the survey guidance in this area, while on the other hand ignoring e-prescribing as a tool that could assist nursing facilities to achieve and sustain compliance.

Yet, CMS' proposed rule is completely silent on the impact of the e-prescribing standards in the LTC setting and thus utterly devoid of any recognition of the importance of e-prescribing to the LTC environment. In fact, the proposed foundation standards would not accommodate the LTC pharmacy services model because the standards are based on direct communication between the prescriber and the retail pharmacy and do not recognize the third critical entity involved in providing drugs in the LTC setting -- the LTC provider. Likewise, CMS has also failed to provide any consideration of how e-prescribing standards might require modification and further development to meet the complex operational and regulatory environment of LTC facility pharmacy services and the role of the consultant pharmacist, or addressed how the development and adoption of LTC e-prescribing could be supported and incentivized. Thus, CMS has not raised the issue of protection for LTC providers under the Anti-kickback statue related to certain e-prescribing incentives -- protection which the Office of Inspector General (OIG) intends to afford other providers, such as physicians, in further regulation.

It is also clear that if CMS hopes to substantively increase the participation of physicians in e-prescribing for Medicare patients, it cannot ignore the LTC patient population. Failure to address the LTC environment in the development of e-prescribing can have serious adverse consequences: it could disincentivize and impede physicians who have LTC patients from adopting e-prescribing technology and or it could disincentivize physicians from caring for LTC patients, thus exacerbating a bias that exists today. Without concurrently including LTC in physician e-prescribing efforts, chemotherapeutic care for the chronically ill will continue to be delivered in a silo, devoid of all benefits from instant information exchange, leaving the physician to deal with e-prescribing for one set of patients and continued use of phone and fax for others. Having physicians using multiple medication systems is confusing, burdensome, costly and will lead to error. This

situation, alone, has the propensity to derail physician e-prescribing technology efforts.

In the final e-prescribing rule and in its future activities in this area, CMS must rectify the omission of consideration of LTC and LTC residents. To that end, we recommend below several steps that CMS should take.

Development of Standards for the LTC Facility Environment

First, we ask that CMS work with the National Council for Prescription Drug Programs (NCPDP) on standards that will make possible and promote e-prescribing in the LTC environment. CMS has adopted the prescription SCRIPT standard of the NCPDP and certain NCPDP standards for eligibility. These final standards are referred to as foundation standards by CMS because they would be the first final set of final standards adopted for an electronic prescribing program. According to CMS adequate industry experience exists with respect to these proposed standards thus allowing CMS to propose and adopt these foundation standards as final standards without pilot testing. However, these standards, based on direct communication between the prescriber and the retail pharmacy, do not accommodate the LTC pharmacy services model. NCPDP has developed a work group to address e-prescribing in the LTC environment. We ask that CMS work with the group developed by the NCPDP to provide design alternatives for standards used within the LTC setting. We understand that the design alternatives being examined by the work group are focused on accounting for and connecting all three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility.

In order to ensure that futher e-prescribing standards work within the context of the three-way prescriber, LTC provider, LTC pharmacy environment, AHCA recommends that additional standards, as well as updates and revisions to e-prescribing standards be subject to formal agency rulemaking. E-prescribing standards represent substantive responsibilities for LTC providers, prescribers, and LTC pharmacies, and a Notice of Proposed Rulemaking (NPRM) process is the only way LTC providers can be assured of notice and an opportunity to comment on e-prescribing standards that affect the services provided to nursing home residents.

As CMS knows, the LTC facility bears the primary responsibility for safe and effective drug distribution to its residents. For example, the requirements with respect to nursing facilities are manifold and strict, as they should be. The core mandate is that "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being in accordance with the comprehensive assessment and plan of care." 42 CFR 483.25. Further, "A drug whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort

or endangers his or her health and safety, then this requirement is not met." 42 CFR 383.60 and 483.75(h). In addition, as a vital part of the quality of care requirements, the facility must ensure that it is free of medication error rates of 5 percent or greater; and residents are free of any significant medication errors. 42 CFR 483.25 (m).

As indicated above, these regulatory mandates place the ultimate responsibility for safe and effective drug distribution with the LTC facility. A critical aspect of this responsibility is the fact that the medical record of the patient is kept at the LTC facility. Thus, a key operative concept in designing an operative LTC e-prescribing system is to acknowledge the responsibilities of the LTC facility, the role of the LTC facility as the guardian of the resident's medical record, and the key role of LTC facility staff.

The act of prescribing in the LTC facility environment involves direct communication between LTC nursing staff and the physician and further communication between the LTC facility staff and the LTC pharmacy. No matter how streamlined the process may become, the LTC facility stands at the heart of the process. Again, this is a model that involves three entities: the physician, the pharmacy, and the LTC facility. Any e-prescribing system that provides the benefits of e-prescribing to LTC residents must involve all three entities.

Most importantly, the system must facilitate and support the ability of the LTC facility to provide the highest quality of care for its residents and meet all of the mandates of law and regulation pertaining to the provision of pharmacy services. Thus, to reiterate, we ask that CMS work with the NCPDP designated workgroup to provide design alternatives for standards used within the LTC profession which will address the vital roles of the three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility. As CMS moves toward full implementation of electronic prescribing for medications covered under Medicare Part D, it is essential that the proper framework be developed for prescribing medications for LTC residents.

Pilot Testing and Demonstrations

Secondly, the MMA requires pilot testing for initial standards for which adequate industry experience is lacking. Testing of such standards would, pursuant to the proposed rule, occur during the 2006 calendar year. The results of the pilot project would be evaluated and, based upon those results, final standards will be published not later than April 1, 2008. The proposed rule indicates that in order to conduct the pilot project, the Secretary will enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals will electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with these standards. The Secretary is mandated to conduct an evaluation of the pilot project,

and to submit a report to the Congress on the evaluation, not later than April 1, 2007. Again, there is no inclusion of LTC providers.

We reiterate our request that CMS work with the NCPDP to develop and pilot test standards that are appropriate for the LTC environment. We are concerned that any pilot study will not provide a true picture of standardization needs for electronic prescribing unless the pilots include the full spectrum of health care, including long-term care. AHCA also recommends that the evaluation of the pilot testing specifically address the experience of physicians, LTC providers, and LTC pharmacies in its report to Congress on the outcome of the pilot testing.

Lastly, we ask that CMS use its demonstration authority to develop and test various appropriate e-prescribing models in LTC facility environments.

Overcoming Barriers to E-Prescribing

Third, CMS must help LTC overcome barriers to the development and application of LTC e-prescribing. In the proposed rule, CMS clearly recognizes the barriers to increased usage of e-prescribing by physicians. One major barrier is the cost of buying and installing a system which includes the time involved in training staff and changing record systems from paper to electronic. CMS also cites lack of reimbursement for e-prescribing costs and resources. Since CMS does not address the LTC environment, the agency never discusses the fact that such costs also will be borne by both LTC facilities and LTC pharmacies in evolving toward e-prescribing.

CMS should first assist the LTC profession in trying to estimate and quantify these costs and then work with LTC providers and pharmacies to find ways to assist the funding of this new technology. For example, with regard to physicians, CMS acknowledges that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees. CMS states that the OIG will create an exception to the Stark law and an Antikickback safe harbor for such e-prescribing physician incentives. If health plans consider similarly incentivizing LTC pharmacies and facilities to join physicians in the three-way LTC e-prescribing environment, then CMS and the OIG should consider similar legal protection for LTC facilities and pharmacies.

Lastly, as we have indicated above, a concomitant barrier to overall adoption of e-prescribing is prolonging an environment in which physicians would face having to use multiple prescribing systems: with e-prescribing for one set of patients and continued use of phone and fax for others. Thus assisting the LTC profession to meet the costs of participating in e-prescribing will help to hasten the adoption of this critical system by all physicians.

CMS Support for LTC Profession Efforts in Information Technology, Adoption of Electronic Records and E-prescribing

Last but not least, e-prescribing is only one facet of the overall revolution that is occurring in the development and adoption of health information technology and the development of electronic health records (EHRs). AHCA is at the forefront of an intensive comprehensive effort to support the development of electronic records and their adoption by LTC providers and the development of appropriate and necessary health information technology (HIT) for introduction to, and adoption by, LTC providers. We are on record with many efforts in these areas.

CMS itself acknowledges that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive EHR system with decision support functionality and that it must be interoperable with other functions of an EHR. CMS indicates that the need for interoperability between these systems will become even more critical in the future when patient medical history standards are adopted. CMS acknowledges that one option might have been to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time.

However, CMS rejected this approach since it would postpone the implementation of any e-prescribing functionality, including the attendant benefits and was beyond the scope of the MMA. Instead CMS is attempting to propose foundation standards that are appropriately accredited and have adequate industry experience. CMS believes that this will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. CMS solicits comment on this approach, as well as on other critical success factors for assuring interoperability.

We agree with this approach since it is our belief that movement forward must be made on all these fronts -- but not without LTC -- and not without the support of CMS as AHCA proceeds with its many initiatives. For instance, we are identifying, reviewing, synthesizing and distributing existing steps/protocol for selecting software, systems and vendors; identifying the need for additional or enhanced criteria to improve the selection protocols; organizing an LTC summit bringing together LTC operators, vendors, and government officials; identifying products available and trying to resolve impediments to product development; collaborating on the Continuity of Care Record (CCR) as part of our EHR initiative; reviewing and commenting on HL7 EHR standards; and promoting LTC profession's efforts to align with Regional Health Information Organizations (RHIOs). This includes monitoring barriers preventing LTC from participating and helping AHCA affiliated state associations efforts to promote LTC partnerships with RHIOs.

Conclusion

In conclusion, LTC residents deserve the finest quality care possible. LTC providers have made enormous strides in improving and enhancing that care. They cannot be left behind as technological innovation is increasingly introduced into the health care environment. The LTC profession assisted by AHCA is taking giant steps in promoting the development of and access to quality enhancing technology.

In the final rule, CMS should address e-prescribing standards that would apply to the provision of pharmacy services in the LTC profession. Further it should articulate the ways and means that it would employ to promote and support e-prescribing in the LTC facility environment. This may include pilot testing, demonstrations and encouragement of health plan support for incentivizing LTC facilities and pharmacies to participate in e-prescribing. I would gladly work with you on these issues and welcome discussion with you on inclusion of the LTC in CMS' e-prescribing efforts.

Sincerely,

Hal Daub
President and CEO

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April 5, 2005

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Re: CMS-0011-P; Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Administrator McClellan:

I am writing on behalf of Pfizer Inc. a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. We appreciate the opportunity to comment on the Medicare E-Prescribing Proposed Rule,[1] and look forward to working with the Centers for Medicare & Medicaid Services (CMS) to ensure that its provisions are implemented in a manner that best meets the needs of patients.

I. BACKGROUND

Pfizer strongly supports the principles of electronic prescribing outlined in the Medicare Modernization Act of 2003 (MMA) and discussed in greater detail in the Proposed Rule. We believe that electronic prescribing offers significant potential to improve the quality of healthcare by reducing medication errors, improving process and cost efficiencies, and increasing patient therapeutic compliance. Looking forward, we also believe that electronic prescribing may serve

[1] See 70 Fed. Reg. 6,256 (Feb. 4, 2005).

as a beachhead for the adoption of electronic medical records and the electronic interchange of health information between interoperable healthcare systems.

Consequently, Pfizer has been very involved in the debate surrounding e-prescribing and the standards that will govern the process. In 2004, we testified before the National Committee on Vital and Health Statistics (NCVHS) regarding a number of specific policy and process concerns that were addressed in the MMA regarding inappropriate messaging and the potential for abuse of e-prescribing technologies. We presented the committee with examples of various behaviors, based on our experience with e-prescribing vendors and technologies, demonstrating the risks of failing to address these issues. Pfizer also submitted comments to CMS as part of the rulemaking process surrounding the new Medicare Part D outpatient prescription drug benefit that, while supporting the e-prescribing program in general, again highlighted our policy and process concerns. Therefore, we were quite concerned that the Proposed Rule made little mention of these issues, focusing instead on the technical standards necessary to transmit information among prescribers, dispensers, and payers. As described below, while Pfizer is strongly supportive of e-prescribing, we remain concerned that the autonomy of the patient-physician relationship may be adversely affected if standards are not designed and evaluated so as to avoid the inappropriate use of e-prescribing and its accompanying technologies.

II. THE PROPOSED RULE

A. We Strongly Support the Use of Pilot Testing to Assess and Evaluate Potential E-Prescribing Standards

Pfizer believes that pilot testing of all e-prescribing standards is necessary to ensure that such standards honor the intent of Congress that physician – and consequently patient – autonomy not be adversely affected by the use of new technologies. E-prescribing, as envisioned by the MMA, will operate on an unprecedented scale. Recognizing this, Congress provided in the MMA for a specific, detailed methodology for developing, recommending, and testing e-prescribing standards. Specifically, the MMA directed CMS to engage NCVHS to assist in developing recommendations for uniform e-prescribing standards, and then to "develop, adopt, recognize, or modify initial uniform standards" based on these recommendations.[2] Next, as noted in the Proposed Rule,[3] CMS is to conduct a voluntary pilot project in 2006 to test its initial standards, to evaluate the results of the test, and to report the results to Congress by April 1,

[2] 42 U.S.C. § 1395w-104(e)(4).

[3] 70 Fed. Reg. at 6,228.

2007.[4] Final standards are due by April 1, 2008.[5] We believe that this process should not be circumvented by implementing standards prematurely without pilot testing.

To assist in this process, Pfizer has played an active role in the discussions surrounding the scope and goals of the 2006 pilot testing program. We recently provided the agency with a number of recommendations for its consideration in developing the pilot projects, including a recommendation that CMS pilot test all e-prescribing standards, including the foundation standards discussed below.[6] Many physicians will not voluntarily adopt e-prescribing unless sufficient evidence exists demonstrating its safety for patients and its affordability for their practices. Pilot testing therefore is absolutely critical to ensure that any proposed standards, including the proposed foundation standards, will function on a practical level as Congress intended and are widely adopted by physicians.

B. We Support CMS's Proposed Industry Experience Criteria and Foundation Standards

While not supplanting the need for pilot testing, Pfizer also supports CMS's proposed criteria for evaluating industry experience with potential e-prescribing standards. In particular, we support the use of ANSI accreditation as an important element in evaluating the industry experience that will be necessary before an e-prescribing standard is promulgated. As noted in the Proposed Rule, the ANSI accreditation process is accessible to all interested stakeholders.[7] This process provides a framework for ensuring that all stakeholders are able to participate in shaping the standards, which in turn increases the potential that any final standard will address and be responsive to industry needs.

We also agree that any e-prescribing standard should be widely implemented by those entities that will be subject to the electronic prescribing requirements and should be recognized by key stakeholders as an industry standard.[8] Industry implementation is crucial to ensuring that any proposed standard will be capable of operating in real-world settings. Similarly, broad industry recognition is important to ensure that the standard is commercially viable, and not

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[4] See 42 U.S.C. § 1395w-104(e)(4)(C). CMS may only forgo the pilot project if it finds there is sufficient industry experience with respect to the initial standards. See id. § 1395w-104(e)(3)(C).

[5] See id. § 1395w-104(e)(4)(D).

[6] See Tab A.

[7] See 70 Fed. Reg. at 6,261.

[8] See id.

simply one of many "standards" currently in use that may not survive if the industry subsequently coalesces around a single standard.

Significantly, while we believe the technical standards proposed as foundation standards, the NCPDP SCRIPT and Telecommunication standards and the X12N 270/271 standards, satisfy these proposed requirements, pilot testing is appropriate because of the lack of industry experience operating these three standards together and within the context of an entirely new Medicare prescription drug benefit program. We are concerned that joint usage of these standards may generate complications or other issues not present when the standards are used individually that, in turn, could discourage physicians from participating in the program. Therefore, the proposed foundation standards should also be subject to pilot testing in 2006.

C. Future Standards Should Provide Appropriate Safeguards to Protect Patients

1. CMS Should Conduct Further Rulemaking and Pilot Testing Prior to Adopting Formulary and Medication History Standards

In the Proposed Rule, CMS indicates that it may adopt formulary and medication history standards as foundation standards if certain criteria, referred to as "critical characteristics," are satisfied.[9] CMS also specifically states that the RxHub protocols may serve as the basis for such standards and solicits comment on this and other candidate standards.[10] Pfizer has a number of concerns about this proposed action.

First, the Proposed Rule does not provide sufficient information to allow stakeholders to submit informed comments on this issue.[11] Other than discussing the possible use of the RxHub protocols as the potential basis for formulary and medication history standards, the Proposed Rule merely identifies the critical characteristics that CMS proposes to use to evaluate such standards.[12] This proposal does not provide any specific guidance as to what final standards CMS may ultimately adopt. Thus, to adopt final standards based solely on this discussion would deprive the public of the ability to submit meaningful comments. We urge CMS instead to review the comments it will receive on the proposed critical characteristics and then propose specific standards for formulary and medication history data for public comment and pilot testing. This will ensure that the greatest number of interested stakeholders can participate in

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[9] See id. at 6,263.

[10] See id.

[11] See id.

[12] See id. at 6,263-64.

this process and provide relevant comments to the agency. If CMS ultimately adopts formulary and medication history standards without explicitly providing specific standards for public consideration and without pilot testing such standards, the careful deliberative process envisioned by Congress would be severely compromised.

We also believe that the RxHub protocols should not be used, either as standards themselves or as the basis for formulary and medication history standards. Currently, the RxHub protocols do not satisfy the proposed criteria regarding industry experience and recognition so as to merit adoption without pilot testing. We understand that these protocols are used in a significant number of formulary transactions; however, these transactions are currently conducted among a limited number of entities in a controlled environment. By comparison, the NCPDP SCRIPT standard is widely used across the entire industry by a variety of stakeholders and stakeholder types. Further, the original RxHub protocols that were submitted to NCPDP for accreditation have undergone substantive changes during task group development and review, and the industry has very limited experience with the current versions. Consequently, we do not believe the RxHub protocols should be adopted as standards, or as the basis for standards, without pilot testing.

Further, the RxHub protocols have not received ANSI accreditation, although we understand that RxHub is seeking such status.[13] Clearly, the pursuit of such accreditation is not a substitute for the completed process. Therefore, the protocols should not be adopted as, or as the basis for, foundation standards.

Finally, we are concerned that CMS's critical characteristics fail to consider the above-referenced policy issues identified by Congress in the MMA and its accompanying Conference Report. We discuss these policy concerns more fully below. We urge CMS to expand its critical characteristics – preferably through regulatory language – to include criteria that evaluate whether potential standards adequately address these concerns and to use pilot testing to assess how successfully a potential standard satisfies these additional criteria.

2. Congress Has Clearly Proscribed Inappropriate Messaging

While embracing the promise of electronic prescribing, in enacting the MMA, Congress was keenly aware of the potential threat that this technology poses to patient and physician autonomy and specifically addressed this concern in the legislation. In particular, the MMA requires that electronic prescribing standards "allow for the messaging of information only if it

[13] See id. at 6,261.

relates to the appropriate prescribing of drugs, including quality assurance measures and systems [to reduce medication errors, to avoid adverse drug interactions, and to improve medication use]."[14] Similarly, the accompanying Conference Report states that, under electronic prescribing, physicians should have access to "neutral and unbiased information on the full range of covered outpatient drugs," and that Congress did not intend for e-prescribing "to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians."[15]

Senate Finance Committee Chairman Charles E. Grassley (R-IA) further reiterated this intent in a July 26, 2004 letter[16] to NCVHS. In that letter, Sen. Grassley explicitly pointed to provisions in the MMA that are "aimed at addressing issues that could compromise electronic prescribing programs and the underlying intent of these provisions."[17] In citing the statutory prohibition on unrelated messaging, Sen. Grassley stated that this "provision is intended to preclude the transmission of commercial information and to ensure the presentation of neutral and unbiased information with the ultimate objective of protecting patient choice."[18] He also highlighted the aforementioned Conference Report language indicating that Congress did not intend for e-prescribing to be a marketing tool or otherwise unduly influence physicians' clinical decisions.[19]

Relying on this unambiguous Congressional intent, NCVHS expressly recommended to the Secretary of Health and Human Services that the agency adopt regulations "requir[ing] that e-prescribing messages received through e-prescribing applications be free from commercial bias."[20]

Remarkably, the Proposed Rule addresses these concerns in a single sentence,[21] and does not provide <u>any</u> guidance or criteria by which to judge whether or how a standard is to address these issues. In contravention of the clearly expressed intent of Congress, the Proposed Rule

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[14] 42 U.S.C. § 1395w-104(e)(3)(D).

[15] H.R. Conf. Rep. No. 108-391, at 455-56.

[16] <u>See</u> Tab B.

[17] Letter from Sen. Charles E. Grassley, Chair, Senate Finance Committee, to Simon Cohn, Chair, Subcommittee on Standards and Security, NCVHS 1 (July 26, 2004) (hereinafter "Grassley letter").

[18] <u>Id.</u>

[19] <u>See id.</u> at 2 (citing H.R. Conf. Rep. No. 108-391, at 456 (2003)).

[20] Letter from John Lumpkin, Chairman, NCVHS, to Tommy Thompson, Secretary, Department of Health and Human Services 14 (Sept. 2, 2004).

[21] <u>See</u> 70 Fed. Reg. at 6,262,

fails to establish the appropriate parameters around electronic prescribing that are needed to protect patients from inappropriate messaging. Consequently, we strongly urge CMS to develop and implement additional criteria in the regulations that will be considered in evaluating all future e-prescribing standards, including the eventual formulary standards. While CMS could address these issues by simply expanding the critical characteristics discussed in the Preamble to the Proposed Rule, we believe these characteristics should be formalized in regulatory text so as to provide an opportunity for public comment.

a. Inappropriate Messaging Should Be Broadly Defined

In general, we urge CMS to promulgate regulations that will create a zone of autonomy that surrounds the physician-patient relationship and protects that relationship from commercial and other inappropriate messaging. This zone should be protected by carefully crafted policies to ensure that these safeguards are not eroded over time. In this regard, we recommend that CMS adopt a broad definition of inappropriate messaging that would extend well beyond traditional advertising and include any non-clinical messaging from any third party – be it a payer, PBM, pharmacy or manufacturer – that is aimed at influencing a physician's choice of drug therapy at the point of prescription or at the point of a patient's choice of pharmacy. Electronic prescribing standards should be designed to improve "patient safety; the quality of care provided to patients; and efficiencies . . . in the delivery of care."[22] We believe an appropriate definition would protect the patient-physician relationship without impeding the transmittal of necessary clinical and benefit information, including a drug's formulary position, cost-sharing, and other relevant benefit restrictions.

b. Proscribe Payment Arrangements With E-Prescribing Vendors that Reward Drug Switching

PBMs and prescription drug plans should not pay electronic prescribing vendors to switch prescriptions from the physician's intended selection to a less-costly choice, without specific consideration of the best care for a particular patient. Indeed, e-prescribing vendors should be completely barred from entering into arrangements under which the vendor receives any financial incentives for influencing physician decision-making. We recognize that, in some instances, the preferred formulary drug may achieve the best balance of clinical and financial value for the patient. In other cases, however, there may be drugs that are on-formulary but not preferred, or are off-formulary, which better serve the patient's needs. In these instances, the physician should not be harassed by communications that attempt to persuade her to select a

[22] 42 U.S.C. § 1395w-104(e)(3)(B).

certain drug because it is financially more appealing to the electronic prescribing vendor, PBM, or other stakeholder. Such communications should be prohibited by regulation.

c. No Interruptive Messages

In addition, the regulations should flatly proscribe interruptive or "pop-up" messages that try to reverse a physician's intended selection at the point of prescription.[23] We strongly believe that a physician and her patient should be advised of all clinical and financial issues related to the writing of a prescription prior to making this decision, and that such information should be presented in a passive, non-interruptive, manner. Once a physician has made an informed selection, pop-up messaging should not be used to seek to change the physician's prescribing decision solely on the basis of financial considerations. Electronic prescribing standards that would allow for this conduct would fail to achieve the congressionally prescribed objectives for such standards.

d. Restrict Pre-emptive Messaging

Pre-emptive messaging, i.e., communications that inform the physician up front that a particular drug is recommended for a particular condition, is also problematic. Such messaging presumably is premised on a relationship between the vendor and either the manufacturer or PBM. It would be reasonable for a vendor to engage in this kind of communication if this messaging is provided independent of any prescription that is being considered for a specific patient. However, if the messaging is being targeted to the physician because she has indicated she is about to prescribe a drug from a certain category, this clearly would be inappropriate and would constitute unrelated messaging that is proscribed under the MMA. Consequently, such messaging should be prohibited because it intrudes on the prescribing transaction and thereby invades the autonomous physician/patient relationship.

e. Present Formulary Information in a Neutral Manner

Reflecting the requirement for e-prescribing under the MMA that the physician have access to "neutral and unbiased information on the full range of covered outpatient drugs,"[24] formulary information, to the fullest extent feasible, should be communicated to prescribers in a single, consolidated neutral list.

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[23] Such a prohibition should not include messaging related to patient education or compliance programs that is presented after the physician prescribes a drug but that does not attempt to influence the prescribing decision.

[24] H.R. Conf. Rep. No. 108-391, at 455 (see also Grassley letter, at 1).

We believe that "neutral and unbiased" presentation means that, when a physician prescribes a drug, she should be presented with all pertinent information at the point of prescription, including all of the drugs that may be used to treat a patient's condition. This list should include all of the plan's preferred drugs, but also drugs that are non-preferred or off-formulary. But physicians should not be shown only the preferred drug and then forced to click again to view non-preferred and off-formulary options. If only the preferred choices are presented, it could unduly influence the physician's selection before she has been fully informed of the complete range of choices and may make it less likely that the physician will consider non-preferred drugs that, while not offering the PBM the highest rebate, could be more beneficial to the patient. While accurate formulary information helps inform the physician's decision, formulary presentation should not be used to exert untoward influence on the prescribing process, nor should PBMs or plans be allowed to provide incentives to e-prescribing vendors to structure the interface in a manner that improperly influences the prescribing decision. Additionally, drug information presented within the electronic prescribing environment should be properly sourced and subject to the same rigorous standards of accountability and balance as required by the FDA for pharmaceutical manufacturers.[25]

D. CMS Should Support the Development of Standards for Real-time Prior Authorization

While we recognize that the Proposed Rule does not specifically address prior authorization, we encourage the agency to consider the implications of the present rulemaking on the future development of a real-time, electronic prior authorization standard, particularly in relation to the potential development of a formulary standard.

Prior authorization was the subject of significant discussion at the NCVHS hearings conducted in 2004. In particular, committee members discussed the impact that providing electronic prior authorization may have on "removing a barrier to . . . a level playing field" in e-prescribing.[26] Pfizer is concerned that Part D plans could utilize prior authorization as a means to inappropriately steer physician decision-making by providing electronic notification that prior authorization is required, but requiring the physician to obtain such authorization via non-electronic means (e.g., faxes, phone calls). To ensure that prior authorization is not used in this

[25] Of course, any restrictions on commercial messaging of the kind described above are rooted in the clear intent of the MMA to protect patient health and safety, and the integrity of both the physician-patient relationship and the discrete prescribing "transaction" itself. This is fully consistent with Pfizer's support for the principle of free exchange of information in a variety of other contexts.

[26] Transcript, Meeting of Subcommittee on Standards and Security, NCVHS (Aug. 19, 2004).

manner, CMS should require that, in addition to the basic formulary information, Part D plans provide specific prior authorization requirements electronically, including the clinical requirements and method for receiving an approval code, to the prescriber at the point of prescription.

Full support for electronic prior authorization is not possible at this time as the complement of standards that would electronically enable the entire process are still under development. However, Pfizer believes that, as an interim measure, any proposed formulary and benefit standard should provide some degree of electronic prior authorization support. For example, the proposed NCPDP formulary standard contains message fields that could be used to provide drug-specific information on prior authorization requirements. The proposed standard also contains a resource link that could be used to provide a web link that would allow the prescriber to complete and submit a prior authorization request. While this approach would only provide an interim solution on the road to full electronic prior authorization, CMS should require that Part D plans utilize these elements of the proposed standard until full support for electronic prior authorization can be developed through pilot testing.

E. CMS Should Develop Guidance for Updating E-prescribing Standards to Reflect Advances in Technology

As the agency undoubtedly knows, technology is not stagnant. New versions of software and hardware are constantly being developed. Even within an industry, not all stakeholders operate with the exact same technology. For example, some entities may use Microsoft Windows 98, while other may use Windows XP. Pfizer believes that e-prescribing standards will be subject to similar evolution and range of use. Consequently, CMS must develop and implement a methodology to incorporate newer versions of existing standards as they are developed without requiring the entire industry to move lockstep and without resorting to formal rulemakings for each change.

In this regard, we specifically recommend that CMS work with Standards Development Organizations (SDOs) to determine the number of versions of standards that may be accepted as "active," as well as when new versions should be adopted and when old versions should be retired. For example, when a new version of a standard is accredited by an SDO, the SDO would vote to present the new version to CMS. Instead of undertaking a formal rulemaking procedure, the new version could be presented to NCVHS for public comment and balloting in conjunction with the formal SDO balloting procedure. If both bodies approve the new version, it would be forwarded to CMS, which would announce the new version in a Federal Register notice. We recommend a similar process for retiring old versions.

III. CONCLUSION

We appreciate the opportunity to comment on these important issues raised by the Proposed Rule, and urge you to address these concerns in a manner that fully protects the patient-physician relationship and otherwise furthers the underlying purposes of the MMA. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,

Charles Lucas

W. Charles Lucas
Senior Assistant General Counsel

From: Martin, Ross
Sent: Thursday, February 24, 2005 6:11 PM
To: Maria A. Friedman D.B.A. (mfriedman@cms.hhs.gov)
Cc: 'ktrudel@cms.hhs.gov'; simon.cohn@kp.org; Jeff Blair (jeffblair@medrecinst.com); Stanley M. Huff, MD (email - coshuff@ihc.com); 'Harry.Reynolds@bcbsnc.com'; 'jwarren2@kumc.edu'; 'sns6@cdc.gov'; J. Michael Fitzmaurice, PhD (mfitzmau@ahrq.gov); David Brailer MD, PhD (david.brailer@hhs.gov); D. Clay Ackerly (dackerly@cms.hhs.gov); Carey, Chris; Glasser, Allison; Labkoff, Steve; Ho, Yin; Friede, Arnold I.; LaMarca, Lou; Wilson, Anne E; Lucas, Charles (Ny-Legal); Gleason, Brenda; Lukshis, Joe
Subject: Recommendations to CMS on 2006 MMA eRx Pilot Activities

Maria –

Thank you for the opportunity, as presented by Karen Trudel at the last National Committee on Vital and Health Statistics (NCVHS) hearing on electronic prescribing (eRx) standards, to provide comments to CMS as you prepare the RFPs for the 2006 eRx pilots under the Medicare Modernization Act of 2003 (MMA). We are very interested in supporting these pilot efforts as we believe they will provide essential insights to CMS, patients, and the industry as a whole and will be instrumental in aiding CMS in the development of eRx standards that advance the stated goals of the MMA's eRx provisions – namely, to improve patient safety, improve the quality of care provided to patients, and increase efficiencies in the delivery of care.

Knowing that you are in the throes of preparing for the procurement process and are under tight deadlines, we have quickly assembled this set of comments that, we hope, will help you conduct informative pilots where adequate industry experience is lacking. The MMA eRx program will undoubtedly have a profound impact on the entire healthcare landscape. Therefore these pilots can do much more than simply provide insights on the initial set of standards CMS will require for eRx under MMA; they can also help the industry gain a greater understanding of the overall impact of eRx and highlight opportunities for future standards as we progress along this continuum of connectivity in healthcare.

As you may recall from Pfizer's testimony to NCVHS last year, we are basing our perspective on this subject on three core principles – *put patients first; support the clinical judgment of healthcare professionals without controlling them; and ensure the integrity of information used in clinical decision-making.* With these core principles and the primary objectives of the MMA's eRx provisions in mind, we request that CMS conduct pilots in 2006 that will target the following objectives:

- Provide a broad analysis of the entire eRx workflow – including the foundational standards for which adequate industry experience exists – to demonstrate the benefits, calculate total-cost-of-care benefits, identify potential obstacles to widespread adoption, and identify areas where appropriate incentives may be required to ensure adoption.
- Examine the use of RxNorm in capturing prescriber intent when used to bridge between systems using disparate drug knowledgebases.
- Examine the use of the RxFill message to improve patient compliance and outcomes and identify potential mechanisms for ensuring its broad adoption.
- Demonstrate the use of the NCPDP-HL7 mapping work to improve outcomes for patients who are discharged from the hospital setting with prescriptions that will be filled at a retail pharmacy.
- Examine the entire prior authorization process and demonstrate the use of existing and emerging standards from X12, HL7 and NCPDP to support electronic adjudication of prior authorization requests.

In the paragraphs that follow, we outline these objectives in greater detail.

Overall eRx Workflow

While there is extensive industry experience in transmitting prescriptions electronically in general, the proposed foundational standards and the additional eRx requirements under MMA not addressed by the foundational standards have not been adequately tested together in a wide range of settings that represent healthcare delivery today. *Pfizer requests that CMS conduct one or more pilots that incorporate all the foundational standards and the proposed additional standards in order to assess the overall impact of eRx on Medicare and the impact to eRx performed outside of Medicare.* These pilots should, at a minimum, seek to answer the following questions:

- How does eRx for Medicare impact physician practices? CMS could fund time-motion studies to examine in greater detail the changes in workflow, efficiencies gained, and challenges encountered when electronic prescribing is adopted within various sized practices.
- How effectively do eRx tools improve patient care? Since eRx adoption for prescribers is voluntary, CMS will need to "make the case" to doctors about why they should make monetary and non-monetary investments in eRx.
- Where do the costs and benefits of eRx accrue and what mechanisms can be put in place to ensure that incentives are appropriately aligned to counteract any economic disincentives created by electronic prescribing?

If CMS does not address these questions in the pilots, it will be difficult if not impossible to adequately address the stated objectives of the law requiring that these tools pose no undue burden on clinicians.

RxNorm

RxNorm shows promise in providing semantic interoperability between systems using different proprietary drug databases. But the use of RxNorm in real world eRx situations has not yet been established and needs to be tested for comprehensiveness. In particular, eRx transactions using RxNorm as a common orderable drug identifier need to be tested to ensure that the prescriber's intent can be fully captured – especially when characteristics of a medication other than dose form, strength and chemical composition can impact the prescribing decision. Such characteristics include the presence of animal products in a medicine or allergens such as egg products or preservatives in the situation where a patient is unable to consume such products for medical, personal or religious reasons.

Pfizer has been discussing with other members of NCPDP the possibility of modifying the NCPDP SCRIPT standard to include fields that capture the characteristics of a prescribed medication that are not fully captured in the RxNorm code. Such a modification would help fill the gaps identified in RxNorm and alleviate the need for RxNorm to consider every possible characteristic of a medication.

Pfizer requests that CMS conduct pilots to adequately test the ability of both RxNorm and proposed enhancements to NCPDP SCRIPT to provide a bridge between prescribing systems using different databases while fully communicating the prescriber's intent.

Medication Adherence Using RxFill Messages to Prescribers

NCPDP SCRIPT contains fields for providing RxFill notification to a prescriber – a message which can close a feedback loop that has long been left open. Currently, the RxFill message is not used with any regularity because there are no business drivers compelling the pharmacies to send it. The message costs money to send and doesn't provide any substantial benefit to the pharmacy.

If the RxFill notification were included in the eRx transaction process as a matter of routine, it could provide clinicians with a powerful tool in understanding their patient's adherence to a

prescribed therapy. Clinicians could then provide counseling to patients about taking their medications as prescribed and avoid the pitfalls of assuming drug therapy failure and switching medications or increasing dosing unnecessarily. Inclusion and testing of such functionality in the pilots would directly address the MMA's stated objectives of providing prescribers with greater medication history data at the point of care. Given the wealth of data demonstrating the quality gains that achievable through improved medication adherence, the lessons learned in these pilots would also be instrumental in enhancing the quality of care.

Pfizer requests that CMS conduct a pilot investigating the impact of providing routine RxFill messages to Medicare patients – especially those on chronic meds whose long-term outcomes can be improved with increased adherence to prescribed therapies.

HL7 to NCPDP SCRIPT eRx Transactions

Pfizer has played a leading role in coordinating industry efforts to map HL7 and NCPDP SCRIPT electronic prescribing standards. The recent demonstration conducted in HL7's booth during the HIMSS conference was a clear success and generated significant interest among stakeholders that were not involved in the initial project. While we have been able to successfully demonstrate that the exchange of electronic prescription messages between HL7-based systems (i.e., hospitals and integrated delivery networks) and NCPDP SCRIPT-based systems (i.e., retail pharmacies) is feasible, these transactions have yet to be demonstrated in a "real world" setting. Among other benefits, the successful enablement of electronic prescribing between these systems will address a critical and well-recognized gap in advancing patient safety, namely, the patient care handoff that occurs when a patient is discharged from a hospital with prescriptions that are to be filled in the retail setting. It will also provide needed guidance for HL7-based institutions comply with the proposed rules.

The mapping efforts to date have focused on HL7 v2.x and NCPDP SCRIPT v5.1. There is concern among the mapping team that the work done to date will only go so far to assist in making the translation of these kinds of transactions more straightforward. The challenge can largely be attributed to the many customizations that are unique to each implementation of these standards. In HL7 implementations in particular, the use of "z-segments", which allow for implementation-specific messages that are not constrained by a common methodology, make it very challenging for anyone attempting to map their customized HL7-based systems to NCPDP SCRIPT using our current guidance documents as a reference.

Members of the mapping workgroup are hoping to complete our work on the 2.x mapping and move to mapping NCPDP SCRIPT to HL7 v3, which is much more constrained and therefore subject to significantly less variability between implementations. This mapping effort could create mapping guidance that will be much more universally applicable.

At this point, the mapping team needs a tangible goal to target in order to move this work forward at a more rapid pace. *Pfizer requests that CMS conduct a pilot to examine the exchange of eRx messages between HL7-based systems and NCPDP SCRIPT-based systems and include in this pilot a mechanism for publishing the "lessons learned" from the pilot, including more detailed guidance on mapping between the two messaging standards.*

Pilots on Prior Authorization (PA)

As you are well aware, NCVHS received a great deal of testimony on prior authorization and the burden it places upon prescribers who attempt to prescribe clinically appropriate medicines that require PA to their patients. Some recent surveys shed additional light on this issue:

- In a survey of conducted in the summer of 2004 by SureScripts and Physicians Interactive, a research division of Allscripts, 2888 physicians were asked about their attitudes on eRx. When asked to prioritize the potential benefits of eRx on their practices, **decreasing "the hassles associated with prior authorization" was the**

highest ranked opportunity – higher than improved access to prescription history (2), formulary information (8), decreasing calls between pharmacy and prescriber (3), easier renewal authorizations (4), or medication adherence tracking (5). *Source: SureScripts Fall 2004 Newsletter – www.surescripts.com*

- Point-of-Care Partners conducted a survey of 25 executives from large health plans at the behest of Pfizer in November of 2004 to better understand plans' attitudes about PA. Pfizer supported this research in response to testimony from the PBMs that there was little interest among payers to automate PA. We doubted this assertion as health plans, in contrast to drug cost carve-out PBMs, have a greater interest in ensuring that their beneficiaries receive appropriate therapy – even high-cost drugs – when they can serve to reduce the total cost of care (i.e., keep patients out of the hospital, emergency department and operating room). In the survey, **Ninety-six percent of the executives support automation of Prior Authorization at point of care** to reduce administrative costs and increase clinically appropriate prescribing. The most common barriers identified by these executives were the lack of physician office technology and the lack of standards. *Source: POCP. Research in submission*

Congress foresaw the importance of PA on the delivery of pharmaceutical care when it explicitly required inclusion of PA requirements in the scope of information that must be provided to prescribers who use eRx for Medicare Part D beneficiaries. In conducting pilot tests that will be the basis for the next round of eRx standards, we believe CMS has the unique opportunity to facilitate the integration of electronic PA adjudication processes into the eRx workflow. Not only would such a focus be responsive to congressional intent and advance the stated objectives of the statute – namely, higher-quality care and improved practice efficiency, but it would also serve to alleviate the burdens so clearly expressed in the survey results cited above.

During the January 2005 NCVHS Subcommittee hearing, Lynne Gilbertson of NCPDP provided testimony on the initial findings of the recently formed PA task group. The task group is seeking to develop a comprehensive overview of PA and determine where various standards could help to streamline this process. The task group has found that multiple standards from multiple Standards Development Organizations (SDOs) – including X12, NCPDP and HL7 – would be required to effectively adjudicate PA electronically. We have provided greater detail on these transaction standards at the end of this email.

There is a strong need to demonstrate a "soup to nuts" approach to PA adjudication that examines the entire PA flow and the interaction of all the messaging and formatting standards. *Pfizer requests that CMS conduct a pilot examining the entire prior authorization process and the standards that could be used to support this process.* Such a project would need to show several interactions:

- Payers using the clinical guidelines standard to author and structure PA requirements in such a way as to support the aggregation and distribution of PA requirements from multiple benefit plans in a consistent manner.
- eRx vendors uploading the structured PA requirements from multiple plans into an eRx system that can be presented to the clinician at the time of prescribing.
- Prescribers viewing and providing responses to the structured PA requirements during the prescribing process.
    - The structure of the PA requirements will facilitate the ability of the eRx tool to present only those questions that are relevant to the patient in question using branching logic (i.e., not asking the clinician to confirm menopausal status in a male patient).
- Prescribers submitting a complete set of PA requirement responses to a payer in an HL7 clinical document attached to an X12N 278 PA request.
- Payers sending a response to the prescriber's PA request using the X12N 278 standard – including all permutations of possible answers (approval with an accompanying code, rejection with reasons, etc.)

Industry already has adequate experience on the remaining portions of the PA process, including the delivery of the PA approval code from the prescriber to the pharmacy (using the NCPDP SCRIPT standard) and the adjudication of the claim (including transmission of the PA approval code) between the pharmacy and the payer (using the NCPDP Telecom standard). But these capabilities should be included in the pilot to show the entire workflow. The pilot should also examine the overall burden of the current process to prescribers and patients, the impact of the PA process on patient access to clinically appropriate medicines, efficiencies gained when using the proposed standards, implementation considerations, and gaps in the proposed methods for electronically enabling the PA process.

Follow Up

Pfizer has been actively encouraging other industry stakeholders to comment on the pilots by spreading the word about this opportunity to comment at last week's HIMSS conference and during recent NCPDP task group calls. While there has been strong interest in responding, the limited window of opportunity is preventing some from finalizing their comments in time. As a result of these constraints, for example, NCPDP has opted not to comment as an organization, but has encouraged individual companies to provide comments. While we cannot claim to have an official endorsement from these organizations, we believe that the recommendations we are outlining below echo the sentiments of many industry stakeholders and encourage CMS to seek additional comments.

We would welcome the opportunity to discuss these recommendations with you and your staff and provide more detail on any of the points made in this email. We have been very active in the standards work alongside many other industry stakeholders – especially around prior authorization and HL7-NCPDP mapping. The 2006 pilots conducted by CMS will undoubtedly set the stage for eRx – not just for Medicare, but for all of healthcare in the US and abroad. We look forward to helping make an appropriately designed electronic prescribing infrastructure a reality for our Medicare beneficiaries.

Regards,

Ross D. Martin, MD, MHA

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Additional Detail on the Standards Required for Electronic Adjudication of Prior Authorization

Please refer to Lynne Gilbertson's testimony to NCHVS from February 1st, 2005 for an overview of the progress of the NCPDP task group on prior authorization. The following information provides further detail on the standards required for fully electronic processing of PA requests. This set of standards represents one potential workflow strategy among several that could be employed to achieve this goal.

- *X12N 278 for the inquiry and response from prescriber to payer* – This HIPAA-designated standard was designed for procedure/pre-admission authorization and requires numerous workarounds to accommodate eRx. There is little industry experience for using this standard for medication PA. X12, with active participation from NCPDP members, has Work by an NCPDP task group (with participation of members of HL7 and X12) has now begun developing guidance on how the 278 standard could be employed

for this purpose. X12 275 may also play a role in delivering the HL7 claims attachment to the PDP.

- *HL7 Claims Attachment Standard for attaching clinical justification of the PA request from prescriber to payer* – Industry is anticipating HHS' release of its rule on health claims attachments in May of this year. Within the context of PA, this standard would be used as the container for the prescriber's response to the PA requirements as articulated by the payer. The standard is modeled after HL7's v3-based Clinical Document Architecture standard. As stated in testimony by representatives of X12 at the NCVHS hearings, there is little industry experience in employing the claims for this purpose.
- *HL7 clinical guidelines standards (including GELLO)* – One of the most important aspects of streamlining the PA process in terms of ensuring interoperability and greater process efficiency is creating a common structure for the PA requirements. Standardization of the PA requirements structure will help ensure interoperability while still leaving the individual criteria contained within the PA requirements up to the payer. In other words, while an individual PDP may require that a patient be over 55 years old to qualify for a particular medicine, in order for interoperability to be achieved, the PDP will need to ask the question in the same manner as every other PDP ("Pt_age >= 55", for example).
    - HL7's Clinical Guidelines SIG has done a great deal of work on creating the type of standards required for this kind of capability. The structure required for adjudicating PA requirements is actually much simpler than other types of guidelines because these are static, point-in-time requirements that are either true or false at the time of prescribing. There is no need to track a patient's progress through a clinical guideline over time before arriving at another decision point. We presented this need to the Clinical Guidelines SIG at the last HL7 workgroup meeting in January 2005. Several members of the SIG expressed a strong interest in working with us to show how GELLO, a query and expression language being developed through the SIG, and other clinical guidelines standards could be used to meet this need. They are preparing demonstrations of this capability for the upcoming NCPDP workgroup meeting in March 2005. With active participation of the SIG, such a capability could be ready to test in time for the 2006 pilots. These standards are still in the balloting stage and would need to complete the balloting process to become an ANSI-accredited standard.
- *NCPDP SCRIPT Standard*
    - NCPDP SCRIPT already has fields in place for transmitting a PA approval code from the prescriber to the pharmacy after the prescriber has received the PA code from the PDP.
    - NCPDP SCRIPT also has fields in place for transmitting a message from the pharmacy to the prescriber indicating that PA code, in the event that a prescriber sends a prescription requiring PA without a PA approval code, is required.
- *NCPDP Telecom Standard*
    - NCPDP Telecom Standard already has fields in place for transmitting a PA approval code from the pharmacy to the payer.
    - NCPDP Telecom Standard already has fields in place for indicating that a claim is being rejected because the prescribed drug requires a PA approval code.
    - These functions of the NCPDP Telecom Standard are in widespread use and do not, of themselves, require testing.

United States Senate

COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

July 26, 2004

Simon P. Cohn, M.D.
Chair
Subcommittee on Standards and Security
National Committee on Vital and Health Statistics
c/o Maria Friedman, D.B.A.
Centers for Medicare & Medicaid Services
Mail Stop S2-26-17
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Implementation of the Medicare Modernization Act (MMA) Electronic Prescribing Program

Dear Dr. Cohn:

Ensuring that Medicare beneficiaries receive a high-quality, affordable prescription drug benefit was a fundamental goal of last year's Medicare Modernization Act (MMA, P.L. 108-173). The MMA includes several provisions to achieve that objective, including those to promote the broad adoption of electronic prescribing practices.

In crafting the electronic prescribing provisions, Congress sought to address a number of issues that could undermine the potential of improved quality, patient safety, and efficiency that electronic prescribing holds. It is my understanding that the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security is holding hearings to inform its recommendations for the initial uniform standards for the electronic prescribing program. As the Subcommittee continues its work, I want to call your attention to specific MMA provisions aimed at addressing issues that could compromise electronic prescribing programs and the underlying intent of these provisions.

1. **Permitting Use of Appropriate Messaging [42 U.S.C. §1395w—104(e)(3)(D)]:** The MMA requires that electronic prescribing standards, "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse drug interactions, and to improve medication use."

   The provision is intended to preclude the transmission of commercial information and to ensure the presentation of neutral and unbiased information with the ultimate objective of protecting patient choice. The Conference Report clarifies Congress' intent by stating the following:

(a) The conferees do not intend for electronic prescribing, "to be used as a marketing platform or other mechanism that could unduly influence physicians' clinical decisions." H.R. Conf. Rep. No 108-391, at 456 (2003).

(b) The conferees intend, "for prescribing health professions to have ready access to neutral and unbiased information on the full range of covered outpatient drugs available." H.R. Conf. Rep. No 108-391, at 455 (2003).

2. **Real-time delivery of patient information [42 U.S.C. §1395w-104(e)(2)(D)]:** The MMA states that "to the extent feasible information exchanged under this paragraph through electronic prescribing shall be on an interactive, real-time basis." While Congress understands that real-time interaction is an important aspect of highly-developed electronic prescribing programs, we also recognize that some providers will have to take significant steps to acquire that capacity. Since our goal is to promote adoption of electronic prescribing practices, the Conference Report clarifies that it is Congress' intent not to "preclude an entity from participating in an electronic prescribing program by virtue of such entity's inability to transmit information on an interactive, real-time basis." H.R. Conf. Rep. No 108-391, at 455 (2003).

I understand that the NCVHS Subcommittee has a substantial amount of work to complete. I request that you inform me in writing about your efforts to develop interim standards consistent with these provisions. Should my staff have additional questions, I would appreciate your taking the time to meet with them to discuss your response in greater detail. The success of electronic prescribing programs depends on the effective resolution of these issues, and I commend the NCVHS Subcommittee for its commitment to exploring them fully prior to submitting its recommendations to the Secretary. I look forward to hearing from you.

Sincerely,

Charles E. Grassley
United States Senator

cc: Jeffrey S. Blair
Vice Chair
Subcommittee on Standards and Security, NCHVS

#13

April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

ATTN: CMS-0011-P

RE: Comments on Proposed Rule -- Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule

Dear Sir or Madam:

The American Association of Nurse Anesthetists (AANA) appreciates this opportunity to comment on the proposed rule for E-Prescribing and the Prescription Drug Program (70 Fed Reg. 6256, February 4, 2005). The AANA is submitting comments in the area of Provisions of the Proposed Rule, Proposed Definitions.

The AANA is the professional association for more than 30,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs are directly involved in approximately 65 percent of all anesthetics given to patients each year in the United States. CRNA services include administering the anesthetic, monitoring the patient's vital signs, staying with the patient throughout the surgery, as well as providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 70 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists and plastic surgeons.

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS - FEDERAL GOVERNMENT AFFAIRS OFFICE
The Capitol Hill Office Building, 412 1st Street, S.E., Suite 12, Washington, D.C. 20003
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The AANA recognizes the need for policies and setting standards that are consistent with the Medicare Modernization Act's (MMA) objectives of promoting patient safety, quality of care, and efficiencies and cost saving in the delivery of care. For this reason, the AANA supports CMS' efforts in this area.

PROVISIONS – II. Provisions of the Proposed Regulation, B. Proposed Definitions

AANA Request: That CMS, in issuing the final rule for E-prescribing and the Prescription Drug Program, maintain its current definition of "prescriber" so long as (1) the final definition recognizes States' ongoing discretion in determining which providers may be granted prescriptive authority and (2) the final definition encompasses CRNAs and other providers who are granted prescriptive authority through the State in which they practice.

The proposed rule states, "Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use." (70 FR 6256, 6265, 02/4/2005) While the proposed definition of "prescriber" is technically correct, it does not explicitly reflect that providers who are not physicians, such as CRNAs, are among the "prescribers" included in the definition. It is our understanding that CRNAs would be included in the "other person licensed, registered, or otherwise permitted…" portion of the "prescriber" definition.

Currently, each State has discretion in determining which providers may be granted prescriptive authority. Many states continue to exercise this discretion by granting CRNAs prescriptive authority. The AANA requests that CMS's final definition of "prescriber" remain as proposed so long as the final definition encompasses providers, including CRNAs and others who are not physician providers, who are granted prescriptive authority through the State in which he or she practices.

We thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Director of Federal Government Affairs, Frank Purcell, at 202.484.8400.

Sincerely,

Frank T. Maziarski

Frank T. Maziarski, CRNA, MS, CLNC
AANA President

cc: Jeffery M. Beutler, CRNA, MS, AANA Executive Director
Frank Purcell, AANA Director of Federal Government Affairs

#14

LTCPA Long Term Care Pharmacy Alliance

April 5, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-0011-P Comments on E-Prescribing and the Prescription Drug Program: Proposed Rule

Dear Dr. McClellan:

The Long Term Care Pharmacy Alliance (LTCPA) is pleased to submit its comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on E-Prescribing and the Prescription Drug Program. 42 Fed. Reg. 6256 (February 4, 2005). The LTCPA is an alliance representing the four major national long-term care (LTC) pharmacies, estimated to serve three out of every five nursing home residents and numerous other beneficiaries in institutional settings, through over 500 LTC pharmacies nationwide. In the course of that service, LTCPA and its members have developed a preeminent expertise in providing prescription drugs and related services to this particularly frail and elderly population, virtually all of whom will be affected by proposed regulations on e-prescribing.

CMS proposes to implement a set of "foundation" e-prescribing standards ahead of the statutory timeframe. However, the proposed foundation standards include the National Council on Prescription Drug Programs' (NCPDP) SCRIPT Version 5.0 which do not work in the LTC pharmacy setting. The SCRIPT standards do not accommodate the type of three-way communication that is essential to the services we provide.

Given those concerns, we have numerous comments addressing both foundation standards and the overall proposed regulation in the long-term care context, which, in turn, directly affects the health and well-being of beneficiaries who are residents of LTC facilities. We also suggest a series of proposed solutions to improve the proposed regulations to ensure that medically necessary and appropriate prescription drugs are timely and properly delivered and administered to LTC residents and related populations served by the LTC pharmacy community. We urge CMS to seriously consider the issues we raise in our comments and the solutions we propose.

Our comments are divided into three sections. In the first section, we describe LTC pharmacy and its responsibility for the needs of the residents we serve. We also explain the critical role that LTC pharmacy has come to serve in today's health care system, and the specialized services

that LTC pharmacy alone can provide. Understanding these services is important, in that the functionality and structure of any e-prescribing system must accommodate these services and ensure they are integrated into any comprehensive e-prescribing regime. Section II contains LTCPA's response to the Proposed Rule in light of these specialized services and the three-way proscribing process that occurs in the long-term care setting. Section III summarizes LTCPA's recommendations and expresses our interest in continuing to work with CMS to develop e-prescribing standards that meet the needs of Medicare beneficiaries residing in long-term care facilities and other settings.

I. LONG-TERM CARE PHARMACY AND THE SPECIAL NEEDS OF THE RESIDENTS WE SERVE

Nursing Home and other LTC Residents Today have Specialized Drug Therapy Needs Far Different Than the Ambulatory Medicare Beneficiary. To address those needs, over the past 25 years the LTC pharmacy industry has emerged to serve the unique needs of the nation's most frail elderly persons. CMS, in its Part D rulemaking, has already recognized the fact that LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what a typical retail pharmacy provides today. Because LTC residents' needs, the services currently being provided by LTC pharmacy, and the resulting cost savings to health care delivery all factor into LTCPA's comments to the proposed regulation, we expand upon them below.

LTC Residents Typically Need Greater Drug Therapy. Unlike the typical ambulatory senior, residents in LTC facilities usually are older, in poorer health, and in need of greater care. A 1999 study by Bernabei *et al.* described the typical LTC resident, as follows:

- mean age of residents is 83.1 years;
- 62% of residents were admitted to the LTC facility from an acute care hospital;
- over half of LTC residents had abnormal cognitive function, and only 17% were characterized as independent or required limited assistance in performing the activities of daily living;
- residents typically had three medical conditions, with 45% having four or more and 10% having more than six medical conditions. Typical diseases included cardiovascular clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents had dementia, and 20% were stroke victims; and
- LTC residents were taking an average of 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% were on some type of cardiac medication, and approximately 40% were on an analgesic.[1]

More recently, the 2000 National Medication Usage Study of 63,671 nursing home residents revealed an average of 8.07 routine medication orders per resident, with 41% receiving 9 or more

[1] *See* Bernabei, *et al., Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*; J. 54 Gerontol. A. Biol Sci. Med. Sci. M25 (1999). At the time it was published, the Bernabie *et al.*study and the SAGE database were the only published statistics specific to long-term care structured to capture specific processes of care provided in LTC facilities. *Id.* at M29.

routine medications per day.[2] The most commonly used drug classes were antidepressants (45%), analgesics (30%), antipsychotics (24%) and anxiolytics (11%).[3] The frequency of drug usage does not reflect an overuse of medications, but rather the increased efficacy of today's more advanced medicines, and the significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses.

LTC Residents Typically Need Different Drug Therapies Than Their Ambulatory Counterparts. Not only are elderly LTC residents on more medications, but they require different medications and different types of mediations. More specifically, as a person ages their body processes drugs differently due to their changing metabolism and typical decreases in kidney function.[4] There has been extensive treatment in the literature describing the need for a different formulary for the elderly,[5] and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in these frail elderly people.[6] While these specialized formularies are often not widely known outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

In addition to differing drug needs, LTC patients often require specialized drug intake systems. One LTCPA member has estimated from their Minimum Data Set records of over 400,000 LTC residents that 9.3% of LTC patients cannot swallow and must be tube fed, and an additional 20.5% of residents have difficulty swallowing and must take their medications through capsules, liquids, injectables, or through pills that can be crushed. Oftentimes, doctors are not familiar with the specialized dosage forms that a nursing resident may need, and the pharmacy has to interact with the doctor to modify a prescription (this is but one example of why long-term care pharmacy must be integrated into the e-prescribing regime). While LTC pharmacy today is equipped to handle and manage these specialized needs, the typical retail or other pharmacy or pharmacy benefit manager is not equipped to address these concerns, or properly manage the significant drug requirements of this specialized elderly population.

LTC Residents Receive Enhanced Drug Services. In light of the significant patient needs noted above, both standards of care and federal and state regulations have evolved to provide LTC residents with an enhanced set of services related to their prescription drugs not provided by retail pharmacy. These services include:

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[2] *See* D.E. Tobias and M. Sey, *General and Psychotherapeutic medication Use in 328 Nursing Facilities: A Year 200 National Survey*, 16 Consult. Pharm. 54 (2001).

[3] *Id.*

[4] *See* M. Fouts, J. Hanlon., C. Pieper., E. Perfetto, and J. Feinberg,, *Identification of Elderly Nursing Facility Residents at High Risk for Drug-Related Problems*, 12 The Consultant Pharmacists 1103 (1997).

[5] *Id.; see also* M. Beers, *Inappropriate Medication Prescribing in Skilled Nursing Facilities*, 117 Annals of Internal Med. 684 (1992); A. Stuck, M. Beers, *et al., Inappropriate Medication Use in Community-Residing Older Persons*, 154 Arch. Intern. Med. 2195 (1994); M. Beers, *Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly*, 157 Arch Intern. Med. 1531 (1997).

[6] *See, e.g.*, Omnicare, Inc., *Geriatric Pharmaceutical Care Guidelines, The Omnicare Formulary* (2001). Omnicare is a member of the LTCPA.

1. Unit Dose and Other Specialized Drug Packaging. This packaging serves two important functions. First, the packaging allows for greater quality control of the drugs and dosages to ensure that medications are taken appropriately and without error. Second, the unit dose system provides a uniform and easily managed process for drug delivery through the central distribution point of the LTC nurse, who will actually deliver the drugs to the patient on any given day. The critical nature of this uniform distribution system throughout the facility cannot be overemphasized. LTC facility nurses face a significant challenge in distributing multiple drugs to dozens of patients each day.[7] The specialized drug packaging provided by LTC pharmacy today is a critical system in helping to reduce patient risks of receiving the wrong drugs, or the inappropriate dosages, from a nurse making delivery rounds.

2. Around the Clock "24/7" Delivery. LTC pharmacy also provides round the clock availability, either through delivery services, med-carts and emergency carts,[8] all of which assist in getting patients necessary medications in a timely manner. This service is particularly important in having intravenous medications available for LTC residents, so that they do not have to be transported to a hospital for treatment. It is critical for CMS to recognize the enormous cost savings to the health care system just from this single service.

3. Consultant Pharmacist Services. In addition to providing the drugs, LTC pharmacy also provides a set of services through Consultant Pharmacists, who are able to review and assist in patient drug care. These services include retrospective drug regimen reviews, as required by law,[9] and prospective drug regimen reviews to screen for medical appropriateness of the prescribed drugs and for inappropriate drug interactions.[10] LTC pharmacists also counsel patients, provide information and recommendations to prescribers and caregivers, review patients' drug regimens, present in-service educational programs, and oversee medication distribution services -- all in addition to providing medication. LTC pharmacists also provide a wide range of other primary care services to seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment assessments and support. In this way, LTC pharmacy is the principal defense against medical errors and ensures the highest quality of patient care.

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[7] *See also* R. Tamblyn, *Medication Use in Seniors: Challenges and Solutions*, 51 Therapie 296 (1996). Tamblyn aptly notes that [h]ealth care system policy and practice can have a substantial impact on the drug utilization among seniors." *Id.* at 275. "Although regulatory changes are made in [governmental] drug plan policies to control costs, there is virtually no information on the impact of drug policy interventions on drug utilization patterns and patient outcomes." *Id.* at 276.

[8] Med-carts and emergency carts are pre-positioned medicines provided to the LTC facility for emergency uses. Typically, several thousand dollars of drugs are stored in such carts, which are only used when a patient emergency arises.

[9] 42 C.F.R. 468.60(c).

[10] M. Dashner, S. Brownstein, K. Cameron J., Feinberg, *Fleetwood Phase II Tests A New Model of Long-term Care Pharmacy*, 15 The Consultant Pharmacist 989 (Oct. 2000). The Fleetwood Phase II project also documented the benefits of early pharmacist intervention on identification of high risk patients, interaction with the prescribing doctor, and development of care plans.

Critical for the provision of these important services is the need for the dispensing pharmacy and its consultant pharmacists to have a complete and accurate understanding of the patient's medical conditions, and, more importantly, current drug utilization.[11] Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than retrospective) basis is for there to be a single dispensing pharmacy for any given patient.[12] Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate utilization of prescriptions. The value of these screening services is significant. Bootman *et al.* estimated that Consultant Pharmacist intervention saves $3.6 billion (in 1997 dollars) in avoided drug related problems.[13]

Bootman *et al.* explained their finding that drug-related problems in the LTC context ($4.6 billion with consultant pharmacists, as opposed to $8.2 billion without their services) were a third higher than those he had previously found in the ambulatory setting:

> First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for [drug related problems, or] DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the physiological effects of aging that alter the ability to metabolize certain drug products. Finally, another factor leading to the greater cost of drug-related morbidity and mortality is that once a DRP has occurred in the nursing home patient, there is a greater intensity of care required to treat the DRP. This could be the result of a more severe reaction experienced by the frail elderly or the higher costs of care that occur within the institutional setting.[14]

The Vast Majority of LTC Residents Currently Receive Prescription Drug Benefits under Medicaid, and, As Dual Eligibles, Will Comprise a Significant Percentage of Enrolled and Active Part-D Beneficiaries In The Coming Years. A recently completed Lewin Group study on "Payer -Specific Financial Analysis of Nursing Facilities," published in March, 2002, indicated that 66% of LTC residents are Medicaid beneficiaries, 12% are Medicare beneficiaries (receiving specific Medicare pharmacy benefits, for example, within their "first 100 days") and the remaining 22% receive insurance benefits or are "private pay" patients. These findings are consistent with

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[11] Tamblyn, *supra* at note 6 at 275 (noting that risk of inappropriate drug prescriptions could be reduced 20 to 30 percent by ensuring that primary physicians and pharmacists have "better access to information about all drugs prescribed to patients") (emphasis added).

[12] While current law only requires retrospective drug regimen reviews, the advantages of prospective drug screening are documented in the literature. *See, e.g.*, Dashner, *supra* at note 10.

[13] *See* J.L. Bootman, D.L. Harrison, E. Cox, *the Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities*, 157 Arch. Intern. Med. 2089 (1997). Bootman *et al.*'s analysis did not even account for prospective drug regime reviews which are conducted by many LTC staff pharmacists today. *Id.* at 2096.

[14] *Id.* at 2095.

both the National Health Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for Healthcare Research and Quality. The National Health Expenses Chartbook also indicates that between 1987 and 1996 the number of LTC residents receiving prescription drugs outside of a Medicare or Medicaid benefit declined from 33.1% to 24.4%. Data provided by LTC operators from approximately 3,000 facilities suggest that within six months of entering a LTC facility, approximately 80% of private pay patients become Medicaid eligible and that by the end of a year, 99% of those residents entering as "private pay" patients become Medicaid eligible.

Thus, it is important for CMS to recognize that the vast majority of LTC residents receive Medicaid prescription drug benefits which include access to "medically necessary" prescription drugs. Virtually all of these so-called "dual eligibles" will be auto-enrolled into the Part D program, and will, likely be the most significant cohort of prescription consumers within the first few years of the Part D program. Thus, it is particularly important in this rulemaking that CMS focus upon this class of beneficiaries, and the pharmacies and doctors that provide prescription drugs to them, to ensure that a functional system is implemented.

LTC Pharmacy is Different from Retail Pharmacy. CMS must also recognize that LTC pharmacy is different from the retail pharmacies that are likely to join PDP plans' networks, or those pharmacies contemplated by the MMA as serving the ambulatory Medicare population that will serve as the backbone of the PDP network.[15] In the retail pharmacy setting, a prescriber transmits a prescription directly to the pharmacy on behalf of the Medicare beneficiary. The prescription is filled by the retail pharmacy, (after checking on the enrollment and benefit status of beneficiary, and charging appropriate co-pays,) and delivered to the beneficiary.

By contrast, the long-term care pharmacy must interact not only with the prescriber, but also with the nursing home in which the beneficiary resides. For example, in most cases, the prescription is transmitted to the long-term care pharmacy by nursing home staff. The prescription is then delivered to the nursing home facility, not to the individual beneficiary. The long-term care pharmacist relies on medication records and medical records at the nursing home to check on drug interactions and other contraindications. The nursing home relies on the long-term care pharmacy for specialized packaging, prompt delivery, and the specialized services of its consultant pharmacist.

In addition to dispensing medications, the long-term care pharmacy represents the beneficiary in coverage issues and appeals. Currently, under Medicaid, long-term care pharmacists engage in adjudication with fiscal intermediaries for prior authorization and appeals processes for dual-eligible beneficiaries. As of January 1, 2006, Medicare beneficiaries or their physicians must request coverage determinations from PDPs or appeal those coverage determinations. If a Medicare beneficiary appoints the long-term care pharmacist as his or her representative for grievance, coverage determination, or appeals processes, the long-term care pharmacist also will need to communicate with the PDP to request coverage determinations and, possibly, appeal negative coverage determinations. These responsibilities require access to beneficiaries' medication history and medical history and interaction with staff at the nursing home and the prescribing physician in order to document the need for a particular medication.

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[15] CMS has previously recognized this distinction in its 2002 rulemaking on the ten-proposed discount drug card program . *Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative*, 67 Fed. Reg. 56,617, 56,640 (Final Rule, Sept. 4, 2004).

In summary, long-term care pharmacies have responsibilities for the prescription drug needs of residents of long-term care facilities that are qualitatively different from those of retail pharmacies. These special responsibilities are reflected in the contracts that long-term care facilities enter into with nursing homes, and illustrate the three-way relationship between the prescriber, the nursing home, and the long-term care pharmacy that must, in turn, be reflected in the e-prescribing process.

II. Comments on the Proposed Regulation

A. The Proposed Regulation Does Not Account for The "Three-Way Transaction" Which Is A Part of Every Long-Term Care Pharmacy Prescription Cycle

Before addressing the specifics of the proposed regulation, LTCPA would like to preface its comments by noting that the Proposed Rule does not address the specific locations in which e-prescribing occurs. As long-term care pharmacy providers, our comments are based on our experience as one component of a prescribing process that also includes physicians and nursing home administrators and staff. At each point in the prescribing process, these three entities will interact. Particularly given the anticipated predominance of dual eligibles in the Part D program, and the prevalence of those beneficiaries in long-term care facilities, we believe CMS should expressly recognize and accommodate the needs of these beneficiaries in e-prescribing regulations.

Under the new Medicare prescription drug benefit, physicians will transmit prescriptions to the long-term care pharmacy through the nursing home staff, and the long-term care pharmacy will interact with the nursing home staff to check medication history and medical history records that are kept in the nursing home. Physicians will initiate prior authorization and other coverage determination requests and also can file appeals on behalf of their patients, and these determinations will be communicated to the long-term care pharmacy by the nursing home staff. If the long-term care pharmacist is designated to represent the beneficiary, these requests can be initiated by the long-term care pharmacist on behalf of the Medicare beneficiary, and the long-term care pharmacist will relay the outcome of these requests to both the nursing home and the prescribing physician so that beneficiaries' records can be updated.

The nature of this three-way transaction makes the setting in which e-prescribing takes place an important consideration in CMS' design of e-prescribing standards. In evaluating its proposed regulation, therefore, we strongly urge CMS to depart from a "one size fits all" approach, and to recognize explicitly in its proposed regulation that there needs to be unique and different e-prescribing standards for the long-term care community that function within the three-way transaction construct. We hope that our comments below provide insight for the agency into the unique e-prescribing issues that we face as one party to these three-way e-prescribing transactions, and offer our assistance as CMS develops e-prescribing standards that reflect the needs of prescribers, nursing homes, and long-term care pharmacies.

B. CMS' Proposed SCRIPT "Foundation" Standard Does Not Work for LTC Pharmacy Because LTC Pharmacy Needs an E-Prescribing Standard That Accommodates Three-Way Communication Between the Physician, Nursing Home, and LTC Pharmacy

CMS requests comment on whether a set of "foundation" standards are ready to be implemented ahead of the statutory timeframe, and whether these standards should only apply to Part D eligible individuals enrolled in Part D plans. Section 1860D-4(e)(4)(C)(i) of the Act permits an exception to the pilot testing of standards when the Secretary determines that there is "adequate industry experience" with the standards. After receiving input from various industry entities, CMS proposes to forego pilot testing of the NCPDP's SCRIPT, Version 5.0 (except for the Prescription Fill Status Notification Transaction and its three business cases) and Telecommunication Standard Guide, Version 5.1 and implement them as "foundation" standards ahead of the statutory timeframe.

Although some retail pharmacies may have adequate industry experience with these foundation standards, LTCPA does not believe that the real-world functionality of SCRIPT has been well tested. SCRIPT communicates only between two healthcare entities, the prescriber and the pharmacy. This rudimentary communication capability does not work for LTC pharmacies because the nature of our prescribing process necessitates a three-way communication between prescribers, nursing homes, and LTC pharmacies.

SCRIPT reflects a prescribing physician-to-pharmacy communication, not the three-way communication path that occurs in a long-term care setting. For example, SCRIPT does not support a refill request from a nursing home to a LTC pharmacy, nor does it support an order discontinuation request from the nursing home to the LTC pharmacy. In the long-term care setting, the nursing home and the LTC pharmacy work in tandem and information systems for prescription drugs must include the nursing home in the e-prescribing process.

In addition, nursing homes receive the majority of their admissions from hospitals., and SCRIPT does not capture the robust information transfer that currently occurs between the hospital, physician, nursing home, and LTC pharmacy. A newly admitted LTC resident coming from a hospital stay is likely to have greater co-morbidities, more complex drug regimens, and a need for more complex medications, including infusion therapy. In order to provide proper pharmaceutical care, a prescriber and an LTC pharmacist must communication with other healthcare providers serving the resident. Hospitals and other health care environments use Health Level 7 (HL-7) which allows this type of communication, and SCRIPT is not compatible with HL-7.

Therefore, LTCPA opposes the use of SCRIPT as a foundation standard. Instead, we propose that CMS revise its approach to e-prescribing standards development, including foundation standards, to incorporate the type of three-way communication that is essential in the long-term care setting.

With respect to CMS' request for comments on its interpretation of Congressional intent for the scope of e-prescribing standards, LTCPA supports CMS' view that Congress intended to confine the application of e-prescribing standards only to information regarding Part D eligible individuals enrolled in Part D plans. While some may argue that this view is unnecessarily narrow and that e-

prescribing standards should be required for a broader set of transactions, LTCPA believes the narrow interpretation is the correct understanding of Congress's intent. Developing and implementing e-prescribing standards within the Part D prescription drug benefit is an enormous challenge for the agency, plans, prescribers, and pharmacies, including LTC pharmacies, and is best accomplished by confining these efforts to the Part D Medicare program. LTCPA's member companies want to be prepared to engage in e-prescribing for Part D eligible individuals in a range of settings, including long-term care facilities, assisted living facilities, and intermediate care facilities for the mentally retarded (ICF/MRs). Rather than over-extending the application of these standards, LTCPA believes that CMS should devote its resources to provide technical assistance and monitoring of the implementation of e-prescribing standards within the Part D program.

C. Pilot Testing of Initial Standards Should Include Long-Term Care Pharmacies Participating in PDP Networks

In order to conduct pilot testing of initial standards for an electronic prescription drug program prior to promulgation of the final uniform standards, the Secretary is required to enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards. (Section 1860D-4(C)(iii)). Prescriptions for long-term care residents are written by the physician and sent to the nursing home and then transmitted to the long-term care pharmacy, which, in turn, communicates with the nursing home and prescribing physician. Pilot testing of these initial standards must, therefore, occur in settings where this three-way transaction is integral to e-prescribing processes.

LTCPA believes that the timeframe for the implementation of pilot testing is too short, and must be extended. If CMS intends to implement pilot testing on January 1, 2006, the agency should implement a staggered implementation in which initial standards can be pilot tested as they are developed with input from all parts of the industry. LTC pharmacies would be logical sites for early pilot testing. Moreover, pilot testing in LTC pharmacies will provide the agency with information on the application of these initial standards to entities involved in complex prescribing procedures involving multiple entities as well as information on how e-prescribing standards are working with an institutionalized population of dual-eligible beneficiaries.

LTCPA recommends that CMS pilot test initial standards during the 2006 calendar year in a sample of long-term care pharmacy settings in order to assure that the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies, and that these standards are working in institutional settings where substantial numbers of Medicare dual eligible beneficiaries reside. CMS's evaluation of the pilot testing must also specifically address the experience of physicians, nursing homes, and long-term care pharmacies in its report to Congress on the outcome of the pilot testing.

D. Preemption is Not Appropriate Until CMS Resolves Issues Related to Existing DEA and Other State Pharmacy Regulations

CMS proposes that the e-prescribing standards it develops will preempt State laws when the state law or regulation: (1) is contrary to the standards or restricts the ability of CMS to carry out e-prescribing in the Part D program; and (2) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs. The State law or regulation would have to meet both of these requirements before it is preempted by Federal electronic prescription program drug requirements adopted through rulemaking.

LTCPA believes that it is important to maintain state pharmacy regulations that impact e-prescribing standards until CMS has worked through the issues it identifies in the proposed regulation. For example, CMS acknowledged during the Special Open Door Forum on the Proposed Rule that it is still attempting to negotiate with the DEA on conforming Medicare's Part D e-prescribing standards with DEA regulations for prescriptions for controlled substances. LTCPA recommends that CMS and the DEA resolve this issue prior to CMS promulgating final e-prescribing standards involving controlled substances. LTCPA also recommends that CMS work with states and other insurers that require non-electronic signatures, so that Federal e-prescribing standards do not put long-term care and other pharmacy providers in the position of needing to comply with two sets of standards for prescriptions for controlled substances.

CMS also should not subject to preemption state pharmacy regulations that require the prescription to be first transmitted to the pharmacy. In the long-term care setting, physicians and nursing home staff do not necessarily know a resident's pharmacy benefits and eligibility coverage, which may change based on level-of-care. The long-term care pharmacy industry standard is for the long-term care pharmacies to keep this information. Under Part D, it will be important for long-term care pharmacies to have this information in real time so that they can meet the coordination of benefits requirements for Medicare Part A, B, and D.

Therefore, LTCPA believes it is essential that Federal e-prescribing standards not preempt state regulations that require a prescription to be submitted to the pharmacy by the prescriber (or by the prescriber via the nursing home), rather than first submitted to a pharmacy benefit manager and then to the pharmacy. Long-term care pharmacies operate under this system in states with this pharmacy regulation, and believe that this procedure will help to ensure timely dispensing of prescription drugs for beneficiaries residing in long-term care facilities. LTCPA recommends that state regulations that require a prescription to be submitted to the pharmacy first not be preempted by CMS' Medicare E-Prescribing Standards.

E. Anti-kickback Statute Safe Harbor is Needed as Guidance for LTC Pharmacies

As CMS notes in the Preamble to the Proposed Rule, Section 1860D-4(e)(6) of the MMA requires the Secretary to promulgate regulations that provide for a safe-harbor under the Anti-kickback statute and an exception under the physician self-referral (Stark) statute for certain non-monetary remuneration (in the form of hardware, software, or information technology and training services) related to e-prescribing information technology items and services. LTCPA recommends

that CMS and the Secretary request the Office of the Inspector General to promulgate these regulations for PDP sponsors for pharmacists and pharmacies participating in their networks as quickly as possible (but surely no later than December 1, 2005, so that they can be used when the Part D program begins on January 1, 2006) so that long-term care pharmacies will have guidance on the types of non-monetary remuneration that are not subject to sanctions under the Anti-kickback statute.

LTCPA anticipates that there will be circumstances in which PDP plans or the pharmacies themselves may be interested in providing non-monetary remuneration in the form of hardware and software (e.g. pre-programmed PDAs for prescribing physicians) and training for prescribers and nursing home staff related to e-prescribing. A safe-harbor under the Anti-kickback statute will provide guidance to PDP plans and long-term care pharmacies on the types of non-monetary remuneration that are acceptable under the statute.

F. CMS' Proposed Incremental Approach to Standards Development Is Flawed And Contrary to Law; All Standards Should be Subject to Notice of Proposed Rulemaking

CMS requests comments on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. LTCPA has serious reservations about CMS' proposed "incremental approach" to adopting final uniform standards for e-prescribing, and is particularly disturbed that CMS would consider requiring any additional standards without a Notice of Proposed Rule Making (NPRM) process. Any standard, including the foundation standards proposed in this rule, represents a substantive requirement for Part D plans and, as standards for electronic e-prescribing, will impact the work of prescribers and providers, including long-term care pharmacies. Only formal rule-making processes will ensure that these entities will have an opportunity for notice and comment. The federal Administrative Procedures Act, 5 U.S.C. § 501, *et seq.*, requires no less.

Long-term care pharmacies now serve the vast majority of Medicare beneficiaries in long-term care facilities and our input regarding adequate industry experience must be factored into CMS' assessment of industry experience with any proposed e-prescribing standards. LTCPA supports the standards design criteria outlined in the MMA, particularly the requirement that standards not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists. We believe that the e-prescribing practices in place throughout our member companies help to prevent adverse drug events (ADEs) for the residents of long-term care facilities we serve. Because we serve nursing homes on a 24/7 and emergency delivery basis, instant connectivity between the health care provider, the nursing home facility, the pharmacy and the PDP plan is a goal we support. However, e-prescribing standards must not unduly burden prescribers, nursing homes, or long-term care pharmacies. Therefore, LTCPA recommends that the third proposed criteria for the development of e-prescribing standards be amended as follows: "The standard is recognized by key industry stakeholders, *including long-term care pharmacies*, as the industry standard." We believe this recommendation conforms with CMS' interest in proposing standards that are "vendor neutral" and will ensure that final e-prescribing standards will work for LTCPA members and other long-term care pharmacies.

Any future standards should be subject to formal agency rulemaking, even if CMS decides to forego pilot testing because of adequate industry experience. The National Committee on Vital and Health Statistics (NCVHS) and standards setting organizations may make recommendations to CMS on e-prescribing standards, but only CMS can promulgate standards through formal rulemaking. Section 1860D-4(e)(4)(B) requires the NCVHS to make recommendations for standards, in consultation with standard setting organizations and other entities, to CMS after consultation with organizations and entities. Section 1860D-4(e)(4)(A) requires the Secretary to *take these recommendations into consideration when developing, adopting, recognizing, or modifying* initial uniform standards, which then are to be pilot tested prior to the agency issuing final standards. The only exception to this process, is that the Secretary, after consultation with standard setting organizations and industry users, may decide not to pilot test standards for which there already is adequate industry experience. The exception provided by Congress applies to the pilot testing requirement, not the rule-making requirement. Clearly, Congress intended for CMS to promulgate rules for the adoption of e-prescribing and for other bodies, including NCVHS, to serve in an advisory capacity, not a rule-making capacity.

G. Issues Related to the Electronic Prescription Drug Program

1. Provider and Dispenser Identifiers

LTCPA will cooperate with efforts by CMS to properly identify dispensers. With regard to unique identifiers for prescribers and dispensers in e-prescribing transactions, LTCPA would support either a National Provider Identifier (NPI), should it become available by January 2006, or the continued use of the NCPDP Provider Identifier Number. At present, NCPDP's Provider Identifier Number can identify long-term care pharmacies with the suffix it uses in the Dispenser Identifier. Adoption of NPI for e-prescribing in all likelihood will be a longer process, however LTCPA will work with CMS to implement the NPI should the agency adopt it. In order to facilitate CMS' task of accelerating the enumeration of all providers, LTCPA member companies are willing to provide a listing of long-term care pharmacy providers serving Medicare beneficiaries to the agency.

2. Formulary and Medication History Standards

Although the NCVHS has recommended that CMS use the RxHub protocol as a basis for rapidly developing an NCPDP standard for formulary and medication history, LTCPA opposes any approach that precludes timely three-way interactions between prescribers, nursing homes, and long-term care pharmacists in the e-prescribing process. We believe certain features of RxHub, e.g. automatically sending a non-formulary prescription back to the prescriber, precludes the involvement of the long-term care pharmacy or nursing home in this process. If, for example, a Medicare beneficiary designates a nursing home administrator or long-term care pharmacist to represent him in coverage determinations requests, these entities must know about the drug that the physician is attempting to prescribe so that they can request a prior authorization on behalf of the beneficiary.

CMS proposes a set of characteristics it considers critical for formulary, benefit, and medication history messaging and requests comments on whether these characteristics should be considered for adoption as foundation standards. LTCPA recommends that the critical characteristics for formulary and benefit data standards be amended to reflect the three-way

transactions for long-term care beneficiaries as follows: "The standards permit operation of three-way transactions between physicians, nursing home staff, and long-term care pharmacies."

Moreover, within the long-term care setting, dual-eligible beneficiaries are not subject to premium and co-pay provisions, and it will be important to distinguish these individuals in the e-prescribing process. LTCPA proposes that the standards for formulary and benefit data be amended to include reference to "long-term care dual eligible resident" and "long-term care non-dual eligible resident" categories so that long-term care pharmacies will be able to quickly identify dual eligible residents who are not subject to premiums and co-payments and other residents of long-term care facilities.

3. Drug Information

Residents of long-term care facilities have complicated drug regimens often consisting of 8 or more drugs per day. Electronic prescription drug information that includes information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments is crucial in the long-term care pharmacy setting. Long-term care pharmacies dispense medications on a 24/7 and emergency basis to nursing homes. Having access to this information in electronic format will assist physicians in appropriately prescribing medications, as well as assist long-term care pharmacies to efficiently and safely dispense prescriptions to Medicare beneficiaries in compliance with the Nursing Home Reform Act of 1987 and other industry standards of care.

4. Medical History

CMS notes in the Preamble to the Proposed Rule that NCVHS has not yet provided recommendations on standards for medical history. LTCPA stands ready to work with NCVHS to provide recommendations to CMS on e-prescribing standards for medical history. In the long-term care setting, medical records for Medicare beneficiaries, like all other residents, are located at the nursing facility, not in the physician's office. Accurate, timely, medical histories are essential for long-term care pharmacies to dispense medications to residents of long-term care facilities. Ideally, medical history e-prescribing standards will be interoperable with electronic medical records (EHRs). LTCPA believes that these e-prescribing standards should be subject to rulemaking in order to assure that they, too, will be interoperable with future EHR standards.

H. Internal E-Prescribing Transactions Should Not Be Subject to Standards for Prescription Communications Within Their Enterprise

CMS has asked whether any standards it adopts for prescription communications should be required for internal as well as external transactions. LTCPA agrees with NCVHS' recommendation to CMS that organizations, including long-term care pharmacies, that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise. As we noted, LTC pharmacies engage in specialized dispensing services (e.g. emergency deliveries) not required of retail pharmacies. CMS has recognized these specialized services in the guidance it has developed for long-term care under the Part D benefit. Because our services are specialized, our internal communications reflect the provision of those specialized services. LTCPA is concerned that if standards for prescription communications are applied within an entity that our communication needs will not "fit" a standard

prescription communications template. Therefore, LTCPA recommends that e-prescribing standards only apply to external communications.

I. New Versions of E-Prescribing Standards Should Be Subject to Formal Rulemaking

As noted above, LTCPA is concerned about the process by which standards will be updated, once adopted, and new versions developed and urges CMS to make new or updated standards subject to formal rulemaking. CMS is proposing to use an incorporate by reference update approval process in which CMS will publish an amendment to a standard in the Code of Federal Regulations in the Federal Register. If the updates are technical in nature (e.g. correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction), CMS proposes that the Secretary consider waiving notice and comment. In this case, compliance with an earlier version or the new version would constitute compliance with the standard. If the updates are substantive (e.g. a new function is considered necessary for an e-prescribing transaction), CMS proposes to modify the required standards through notice and comment rulemaking. CMS proposes to base its determination on whether to waive notice and comment on the significance of any corrections or revision and whether the newer version is "backward compatible" with the previously adopted version. According to CMS, "backward compatible" means that the newer version retains the full functionality of the previously adopted version that had been adopted through rulemaking.

LTCPA disagrees with NCPDP's position that the decision to change a standard is dependent on the standards setting organization and should not be constrained by the federal standard version naming process. The NCPCP vetting process is a consensus process, but individual members of the NCPDP may have specific business practices which will be negatively affected by allowing NCPDP to determine the timing and release of new versions of Federal e-prescribing standards. Apparently, NCPDP is interested in avoiding the formal rulemaking process when introducing new versions of a standard. This is not acceptable to LTCPA members.

LTCPA urges CMS to subject all updated and newer versions of e-prescribing standards to the NPRM process. Only by having an opportunity to formally comment on updated and newer versions of Medicare e-prescribing standards will LTCPA be assured that the needs of prescribers, nursing homes, and long-term care pharmacies will be met.

III. Conclusion

In summary, LTCPA recommends that:

- CMS not use SCRIPT as part of its "foundation" standards for e-prescribing within the Medicare prescription drug program because SCRIPT does not accommodate LTC pharmacies' need for a set of foundation standards that reflect the three-way communication that is essential in a LTC setting.

- CMS adopt the view that Congress intended to confine the application of e-prescribing standards only to information regarding Part D eligible individuals enrolled in Part D plans,

and, accordingly, implement these standards only for Part D eligible individuals enrolled in Part D plans.

- CMS pilot test initial standards during the 2006 calendar year in a sample of long-term care pharmacy settings in order to assure that the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and that these standards work in institutional settings where substantial numbers of Medicare dual eligible beneficiaries reside.

- CMS include in its report to Congress, an evaluation of the pilot testing that specifically addresses the experience of physicians, nursing homes, and long-term care pharmacies.

- CMS resolve its issue with the DEA regarding DEA regulations for non-electronic signatures for prescriptions for controlled substances prior to promulgating final e-prescribing standards.

- CMS not subject to preemption state regulations that require a prescription to be submitted to the pharmacy by the prescriber first rather than to a pharmacy benefit manager.

- CMS urge the Secretary to quickly promulgate a safe-harbor to the Anti-kickback statute that will provide guidance to PDP plans and long-term care pharmacies on the types of non-monetary remuneration related to e-prescribing information technology items or services that are acceptable under the statute.

- CMS amend its e-prescribing standards to include: "The standard is recognized by key industry stakeholders, *including long-term care pharmacies*, as the industry standard"

- CMS subject any e-prescribing standards to formal agency rulemaking.

- CMS amend its critical characteristics for formulary and benefit data standards to reflect the three-way transactions for long-term care beneficiaries as follows: "The standards permit operation of three-way transactions between physicians, nursing home staff, and long-term care pharmacies."

- CMS add categories to distinguish long-term care dual eligible and non-dual eligible beneficiaries to its e-prescribing formulary standards.

- CMS apply e-prescribing communication standards to external transactions only and not communications within an entity.

- CMS subject all updated and newer versions of e-prescribing standards to formal agency rulemaking.

LTCPA looks forward to working with CMS in developing Part D e-prescribing standards that work for prescribers, nursing homes, and long-term care pharmacies in meeting the prescription drug needs of Medicare beneficiaries. We would be pleased to meet with CMS staff involved in the development of these standards to further articulate our comments, and also look forward to participating in CMS' plans for piloting the initial e-prescribing standards.

Sincerely,

Paul Baldwin, Executive Director

#15

BlueCross BlueShield Association

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April 5, 2005

The Honorable Mark McClellan, MD, Ph.D.
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Via Electronic Mail

Attention: **CMS-0011-P**

Re: Comments on Proposed Rule: Medicare Program: E-Prescribing and the Prescription Drug Program NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). BCBSA represents the 40 independent Blue Cross and Blue Shield Plans (Plans) that provide coverage to 92 million people – nearly one-in-three Americans – among them approximately one million beneficiaries in Medicare Advantage.

BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries – and also help slow the rate of growth in spending – by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and claims administrators in Medicare Part D.

First and foremost, we urge CMS to change the January 1, 2006 compliance date to give plans the time to build the capacity for e-prescribing and ensure a smooth transition to the national standard. CMS should allow a period of pilot testing before final adoption of standards – as provided for in the statute and as recommended by the Workgroup for Electronic Data Interchange[1] – and a sufficient implementation period after HHS has issued final rules for plans to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the

[1] *See* Letter to The Honorable Tommy Thompson from the Workgroup for Electronic Data Interchange (WEDI), dated March 8, 2004. WEDI supported and recommended the concept of using pilot implementations for future standards. Piloting identifies flaws that could be corrected before issuing final standards and determines if proposed standards actually accomplish intended goals. *Id.* at page 6.
www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/March82004LettertoDHHS.pdf

system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

- BCBSA supports CMS choices of ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, many commercial and proprietary e-prescribing systems currently do not use these standards. It will take time to develop and deploy software that uses these standards, time to test these standards, and time to identify and correct any problems integrating 270/271 and NCPDP standards.

- Performance testing is particularly important for the 270/271 standards because relatively few providers are now originating 270 transactions for claims. For example, 2004 data on HIPAA transactions from Blue Cross and Blue Shield Plans' national accounts and traveling members show that 270 transactions comprised less than 2 percent of total HIPAA transactions.

- For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

In addition to changing the compliance date, BCBSA urges CMS to make two other important changes:

- Adopt a broader view of preemption that federal law preempts any state law. CMS's narrow interpretation of preemption could make e-prescribing administratively difficult for providers, pharmacies, and administrators.

- Follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. CMS's proposal unnecessarily regulates entities' internal processes, thus raising the administrative burden of supporting e-prescribing.

We appreciate the opportunity to offer these comments, which we strongly believe will make e-prescribing administratively practicable for providers, pharmacies and claims administrators, thus strengthening the overall Part D benefit. Please find attached more detailed comments, arrayed to follow the issues as presented in the NPRM.

We look forward to continuing to work with you and your staff on this and all other issues relating to the Medicare Prescription Drug Benefit.

Sincerely,

Alissa Fox

Alissa Fox
Executive Director, Policy

Attachment

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April 5, 2005

Blue Cross Blue Shield Association Comments on
"Medicare Program: E-Prescribing and the Prescription Drug Program"
Proposed Rule
NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)
CMS-0011-P

The Center for Medicare and Medicaid Services (CMS) requested that comments be organized by the section of the proposed rule to which they apply, using the specific "issue identifier" that precedes the section: **Background;** and **Provisions**. The order of these comments follows the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on February 4, 2005.

I. Background

State preemption (Page 6258)

Proposed Rule: The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contains specific statutory language on the preemption of State laws that are contrary to the standards or restrict the ability to carry out the Part D benefit and that pertain to the electronic transmission of prescriptions and information with respect to Part D covered drugs. CMS proposes to interpret this preemption of state laws narrowly, finding that it applies only to state laws that are either contrary to the Federal standards or that restrict the ability to carry out the e-prescribing drug program requirements and pertain to electronic prescriptions and information regarding Part D drugs for Part D enrolled individuals.

Issues: Variations in state rules and regulations are ubiquitous. As explained in a separate letter "Comments on E-Prescribing of Drugs and Preemption of State Laws," BCBSA believes that forcing providers, pharmacies, and claims administrators to comply simultaneously with multiple state rules and the federal rule may deter use of e-prescribing, and unnecessarily raise costs and administrative burden.

BCBSA Recommendation: BCBSA believes that CMS should adopt a more expansive view of federal preemption confirming that federal law preempts any state law that would frustrate Congress' policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D.

Criteria for determining foundation standards (Page 6261)

Proposed Rule: The MMA permits HHS to adopt standards as final without pilot testing where the Secretary can determine there is "adequate industry experience" with the standard. The MMA did not define "adequate industry experience." CMS has proposed the following criteria to assess adequate industry experience:

- American National Standards Institute (ANSI) accredited;
- Generally has been implemented in multiple e-prescribing programs with more than one external partner by entities to which the final standard will apply; and
- Recognized by key industry stakeholders as the industry standard.

Issues: We believe that these criteria are necessary – especially ANSI accreditation – but not sufficient to assess adequate industry experience. The HIPAA transaction experience demonstrates that systems and processes vary greatly, especially around key vendor products. Therefore, implementation in "multiple" e-prescribing programs is no guarantee that a standard can go without testing in all settings; for example, systems that work well for a chain pharmacy model may not work well for independent pharmacies or for mail order pharmacies.

BCBSA Recommendation: CMS should seek additional recommendations from stakeholders on how to assess adequate industry experience. CMS's view that there is adequate industry experience for the proposed foundation standards – a view that we question – is indicative of the need for added criteria.

Identifiers (Page 6262)

Proposed Rule: CMS is considering requiring the use of the national provider identifier (NPI) as the provider identifier for an e-prescription under Medicare Part D. The NPI timetable calls for HHS to begin accepting applications from providers for identifiers after May 23, 2005. Use of the NPI is mandatory starting May 23, 2007 (2008 for small health plans).

Issue: At this time, it appears that the NPI will not be universally available for use by January 2006. For HIPAA NPI implementation purposes, industry has proposed a "workaround" that would allow transactions to carry both the old identifier and the new NPI. However, provider and vendor systems that send billing information to the Plans may not be able to carry both the legacy identifier and the NPI by January 2006.

Plans that did not expect to have to be ready to process the NPI until 2007 may begin to receive transactions with the NPI as the only identifier and other transactions with a non-NPI identifier. Depending on the source of the transaction, plan systems would have to process the transaction using the NPI or a legacy identifier – running and maintaining duplicate systems for the interim period. Plans must be given sufficient time to migrate providers from their legacy identifiers to the providers' new NPI. Additionally, the NPI does not support the necessary transmission routing functions of electronic prescribing identifiers. Current identifiers allow for individual prescriber identification and multiple service locations. A single identifier solution for this shortcoming must be developed, assessed and tested.

BCBSA Recommendation: BCBSA urges that CMS move back the January 1, 2006 compliance date to permit additional time for pilot testing and implementation. This would have the added benefit of avoiding the issues created by an early implementation of the NPI for e-prescribing.

We note that the Workgroup for Electronic Date Interchange (WEDI) recommended in a September 30, 2004 letter to Secretary Tommy Thompson that no successful implementation of the NPI could occur in less than 18 months from the time the NPI is available for use, and that

no full-scale implementation should be undertaken without pilot testing the NPI.[1] We would support pilot testing use of the NPI in the e-prescribing context.

Formulary and medication history standards (Page 6263)

Proposed Rule: The NCVHS determined that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer Protocols established by RxHub. On the basis of this determination and other criteria revealed in the proposed rule, CMS is proposing to adopt other standards currently under development by NCPDP as foundation standards.

Issue: Many Plans that intend to offer Part D benefits use commercial or proprietary formulary and medication history messaging protocols dissimilar to those that will be balloted by NCPDP. Thus, adequate industry experience is lacking.

BCBSA Recommendation: CMS should adopt the formulary and medication history standards currently being balloted by NCPDP as initial standards to pilot test and not as foundation standards for required use beginning January 1, 2006.

Proposed foundation standards (Page 6264)

Proposed Rule: CMS proposes to apply the "adequate industry experience" exception to specific standards regarding prescription transmissions between prescribers and dispensers and eligibility inquiries between dispensers and payors and prescribers and payors (NCPDP SCRIPT Standard, Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5.1; and American Standards Committee (ASC) X 12N 270/271).

Issue: BCBSA supports using ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, industry does not have adequate experience because many current commercial and proprietary e-prescribing systems do not use the 270/271 standards. These e-prescribing systems generally provide eligibility information to the pharmacy using the NCPDP telecommunication standard. It will take time to make enrollee eligibility available to physicians using the 270/271 transaction: time for software development; time for deployment; and time to identify and correct any integration problems.

For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

Lack of adequate industry experience may be a particular issue for mail order pharmacies. Communicating eligibility and benefit status to and from a dispensing pharmacy via the NCPDP telecommunications standard is currently a HIPAA required transaction standard for communications with retail pharmacies. But in mail order pharmacies, prescriptions generally arrive via fax and are entered into the mail-order pharmacy's automated fill-order system. Eligibility is determined by checking against enrollee information provided by a plan directly to the mail-order pharmacy and not through an on-line inquiry system built to the NCPDP

[1] *See* "WEDI NPIPAG Recommendations, August 26, 2004," Issues 1 and 3. A copy of this correspondence can be found at http://www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/093004NPIFinalEDJR.pdf .

Telecommunications Standard. These processes operate on computer programs written to code not interoperable with e-prescribing software.

BCBSA Recommendation: While BCBSA supports the selection of specific appropriate standards for e-prescribing functions, we urge CMS to support a period of pilot testing (for at least one year) to ensure that the 270/271 standards will perform as desired when integrated into an e-prescribing systems with the NCPDP Telecommunication standards. Also, we urge CMS to provide for an implementation period (the statutory timetable would suggest 24 months) that gives plans sufficient time to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

II. Provisions

Definitions (Page 6265)

Proposed Rule: CMS proposes the following definition:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

Issue: The definition reflects the narrow state preemption analysis proposed by CMS to govern conflicts with state laws. Under the proposed definition, an e-prescribing program is limited to Part D drugs prescribed for Part D eligibile individuals who are enrolled in Part D Plans. The adopted standards would then apply only to this narrow set of drugs and individuals.

Recommendation: BCBSA recommends that the definition of a Electronic Prescription Drug Program be revised as follows:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Communication in closed networks (Page 6265)

Proposed Rule: CMS would require e-prescribing communications internal to an organization be communicated in compliance with the adopted NCPDP Script standards for e-prescribing for Part D drugs. The NCVHS had recommended that organizations that conduct e-prescribing internally should not be required to convert to the standards to be adopted by CMS for Medicare Part D for prescription communications within their enterprise. CMS notes that the NCVHS recommendation differs from the HIPAA transaction rule requirement that a "covered entity" conducting a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard HIPAA transaction.

Issue: BCBSA is concerned with CMS' decision not to follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. BCBSA's general approach to health information technology is that transaction rules should not dictate internal processing but should ensure standardizing the interfacing between differing organizations' systems for market interoperability.

BCBSA Recommendation: CMS should follow the recommendations of the NCVHS and recognize that the exchange of prescription information within the same enterprise is outside the scope of the MMA requirements.

Backward compatibility (Page 6267)

Proposed Rule: HHS is proposing to consider waiving notice and comment rulemaking when updates or newer versions of standards are "backward compatible" (i.e., entities using the newer version would be able to complete transactions with entities using the the previous version). In this case, CMS would likely permit the version that was previously adopted and the new version as equally compliant at the same time.

Issue: In general, an entity using the older version of a standard cannot process the newer version without further system changes, such as the addition of translation software – even when the newer version does not include substantive changes such as new functions. True backward compatibility occurs when the entity adopting the new version pays for the translation software. However, the CMS definition of backwards compatibility could be construed as absolving the entity adopting the new version of the obligation of paying for that translation software, thus inadvertently penalizing entities that choose to keep the previously adopted standard.

BCBSA Recommendations: CMS should make clear that the obligation to produce transactions that an entity with a previously adopted versions can process lies with the entity that chooses to migrate to the newer version. CMS should not find backward compatibility where no provision has been made in the standard to ensure that entities with previously adopted versions can process those transactions sent from entities using newer versions.

Linking e-prescribing standards updates to HIPAA standards updates (Page 6267)

Proposed Rule: CMS proposes to coordinate the updating process for those e-prescribing standards that are also HIPAA transaction standards.

Issue: Linking the e-prescribing standard update to the HIPAA standards update would provide administrative simplicity for CMS and reduce the compliance burden for the affected industries and covered entities.

BCBSA Recommendation: BCBSA supports having the e-prescribing standards updates tied to the HIPAA updates. This allows entities to monitor one point for future proposed changes. It also avoids getting HIPAA and e-prescribing out of synch and into conflicting requirements.

Compliance date (Page 6267)

Proposed Rule: CMS proposes making compliance with the e-prescribing standards proposed in this rule mandatory on Part D sponsors and MA/PD plans as of January 1, 2006.

Issue: BCBSA believes that January 2006 is not a reasonable compliance date for implementation of these proposed new foundation standards See "Proposed foundation standards" above

BCBSA Recommendation: See "Proposed foundation standards" above.

#16

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200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-0011-P
Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Dr. McClellan:

Biogen Idec appreciates the opportunity to offer its comments to the proposed rule adopting standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). We are a global leader in biotechnology headquartered in Cambridge, Massachusetts with centers of excellence in San Diego, California and Cambridge. Our products and development programs address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology.

Biogen Idec has reviewed and generally concurs with the July 22, 2004 written comments of the American College of Physicians,[1] particularly with respect to the potential for electronic systems to inappropriately guide physician treatment decisions, the need for prior authorization submission capability, and the concern that formulary, cost, and copayment information be accurate and up-to-date. More specifically:

- The treating physician is in the best position to consider the scientific evidence and his/her knowledge of the patient's medical history in selecting the most appropriate therapy. The standards should enable physicians to select from among all potential therapies (rather than solely from formulary products), and to direct the active ingredient, dosage, formulation, and other specific instructions that may apply to a particular patient;
- For prescribed products that are not on a plan's formulary, the e-prescribing system should direct the physician to potential formulary-listed alternatives, as well as provide message instructions on exception or appeals procedures. The MMA provides exception and appeals mechanisms for instances in which a physician determines that a formulary product cannot be substituted for a prescribed non-formulary therapy; electronic prescribing standards should enable rather than thwart exercise of this important beneficiary protection. The MMA requirement for e-prescription standards on medical history information related to a Part D drug appears designed to streamline prior-authorization and

[1] http://www.acpoline.org/hpp/e-prescribe.pdf

exception/appeal processes rather than to require maintenance and dissemination of more general electronic medical histories;

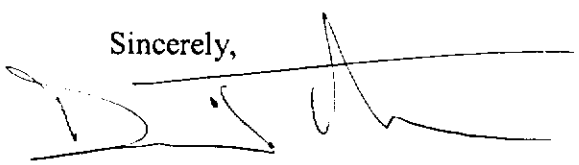
- As the ACP noted, an electronic prescription system will not provide significant benefit to physicians unless it streamlines the prior authorization process into a real-time online adjudication. Prior authorization can be a valuable tool in ensuring appropriate utilization, but can also be used as a hurdle requiring significant provider telephone intervention, additional paperwork, and other tactics to discourage providers from prescribing particular therapies. Most prior authorization requirements contain specific conditions that must be met for coverage of the prescribed therapy. Electronic physician certification of compliance or non-compliance with those conditions (at initial prescription or in response to a denial) should be worked into the messaging capabilities of electronic systems at the start of the pilot program to ensure physician participation and accurately gauge satisfaction.
- Biogen Idec generally supports electronic prescription systems that provide physicians with information on the formulary status, cost, and copayment applicable to a prescribed product. The ACP indicated that many physicians would work toward choosing therapies, in part based upon the cost to the beneficiary. We urge CMS to ensure that the standards are implemented to ensure that this information is accurate and complete for the particular beneficiary. The following examples illustrate potential pitfalls in utilizing general PDP information rather than beneficiary-specific information:
    - For a patient with a chronic debilitating condition, biological X costs $1,000 per month and is tiered for 50% copayment; biological Y costs $1,250 but is tiered for a 20% copayment. The patient and physician are frustrated and wish to appeal. They are told that formulary tier decisions are subject to appeal, except for biologics. Accurate beneficiary-specific information could alleviate frustrations:
        - If the beneficiary has already exceeded or come to close to the out-of-pocket expense maximum, there is, in fact, no difference in cost sharing percent between the therapies. Catastrophic coverage kicks in and the statutory 95% benefit controls for non-low-income beneficiaries.
        - For long-term therapies such as biologics for chronic debilitating conditions, the difference between a 50% copayment and a 20% copayment is simply a matter of whether the patient pays higher amounts for a shorter period of time or lower amounts for a longer period of time. The beneficiary will, over the long-term, pay slightly less for the less expensive therapy regardless of tiering. This is not intuitively obvious from a decision field that does not incorporate the out-of-pocket maximum calculation for a beneficiary.

- A physician prescribes a $500/month pharmaceutical that generally contains a 25% copayment. The physician believes that the beneficiary cannot afford the copayment, but lower-cost alternatives do not exist.
    - Has the electronic prescribing system maintained up-to-date information on the beneficiary's out-of-pocket expenditures to date? Is there messaging capacity to direct the beneficiary to any non-profit organization that might offer cost sharing assistance? Unless the cost and copayment data is complete and captures the beneficiary's complete plan experience, physicians may make compromise medical decisions based upon faulty financial data.

- It appears that the current systems utilizing NCPDP standards do not always contain up-to-date information on formulary changes. A system that generates erroneous information on formulary inclusion or exclusion may prove more frustrating for providers and patients than the current paper script system. Similarly, Biogen Idec is concerned that this potential shortcoming in the electronic system may have the effect of misleading patients and providers on coverage of newer therapies.

Biogen Idec supports CMS in its first steps to implement uniform standards for e-prescribing that meet the MMA goals of patient safety, quality of care, and efficiencies for cost savings in care delivery. As always, we appreciate your thoughtful consideration of our comments and are available to answer any additional questions you may have.

Sincerely,



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April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423)

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to submit comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule on E-prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256 (February 4, 2005).

Current E-Prescribing Environment

Although the concept of electronic prescribing (e-prescribing) appears simple, broad scale electronic prescribing as defined in the Medicare Prescription Drug Improvement and Modernization Act (MMA) barely exists in the ambulatory setting. Some hospitals and large practices can electronically communicate with on-site pharmacies via closed systems, but two-way, interoperable, and secure external systems currently are used only in extremely limited circumstances. Because much of the technology developed to date has been delivered at the desktop for hospital facilities and large group practices, there needs to be more focus on incorporating the specific needs of independently practicing physicians. Standards for advanced e-prescribing systems with "roaming" or wireless capabilities are also needed. Development of a single set of standards appropriate for all health care delivery situations will be a significant undertaking.

The AMA recently conducted a survey with Forrester entitled "Physicians' Use of Information Technology." The results of the survey indicate that implementation of e-prescribing in physicians' practices is currently very low. The following are responses to the question "Has your medical practice implemented an electronic prescribing system?"

- 8.6% reported that their practice has implemented an electronic prescribing system, but only on a limited scale.
- 11.7% reported that they have implemented an electronic prescribing system throughout the practice.
- 14.2% reported that they have not implemented an electronic prescribing system, but have investigated and tested some systems.
- 62.5% reported that they have not investigated an electronic prescribing system for their practice.
- 2.9% reported that they don't know if their practice has implemented an electronic prescribing system.

In response to a related question from the above results "If no, why not?" the following was found:

- 19.8% reported it was due to the high price of e-prescribing products.
- 11.7% reported that technology alternatives do not provide a measurable or justifiable improvement over existing methods.
- 6.7% reported that implementing new e-prescribing products requires extensive resources (e.g., personnel time, cost, etc.).
- 5.5% reported that it was because physicians resist new technologies.
- 5.4% reported that the current hardware/software at the practice is incompatible with e-prescribing products.
- 4.7% reported that there is a lack of e-prescribing products that meet the organizations' needs.
- 4.5% reported the lack of demand from customers (i.e., patients).
- 4.0% reported that it is too difficult to evaluate available e-prescribing options.
- 3.8% reported HIPAA compliance issues.
- 2.8% reported that it was because staff resists new technology.
- 2.6% reported that current e-prescribing products are not user-friendly.
- 2.4% reported there was a lack of buy-in at senior management level.

From the physician perspective, standards for e-prescribing must take into account the wide variety of clinical settings and specialties. We urge CMS to adopt final standards that are flexible and scalable to encourage adoption from small to large health care organizations and low-to high-volume prescribing physician specialties. E-prescribing standards must allow for basic stand alone e-prescribing platforms that permit small practices to meet the regulatory requirements without an undue financial burden. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency, and integration with existing management software and electronic medical record systems before making a further investment for e-prescribing. Physicians should also have the option of using a clearinghouse for e-prescribing, as they do with the standard transactions adopted under the Health Insurance Portability and

Accountability Act (HIPAA), until vendors can provide products that have been tested in the e-prescribing environment and that are interoperable with the physicians' practice management and electronic health record systems.

Standards for e-prescribing are currently deficient in the area of medical vocabulary, yet there does not appear to be a single solution to meet vocabulary needs. The AMA also believes that the terminology supporting patient data should be more comprehensive. For example, one of the suggested e-prescribing nomenclatures is RxNorm. RxNorm is a clinical drug nomenclature that provides standard names for clinical drugs and for dose forms as administered. It provides links from clinical drugs to their active ingredients, drug components, and some related brand names. To the extent available, National Drug Codes (NDCs) for specific drug products that deliver the clinical drug are stored as attributes of the clinical drug in RxNorm. However, the scope of the nomenclature needs to be broadened to account for other details such as packaging sizes, flavorings of oral medications, etc. The standard should more accurately capture "what the doctor ordered". RxNorm may need testing and enhancement before it will be suitable for use in the private sector.

In addition, interoperability with many clinical terms is also very important. For example, some terms may be used differently in a hospital setting than in a physician practice. Final standards may need to be enhanced where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality, efficiency, and to facilitate interoperability between the various electronic systems involved in the e-prescribing process.

The e-prescribing process should permit an entire electronic transaction seamlessly, from beginning to end. A physician should be able to efficiently submit a secure, authenticated prescription electronically in real time to a payer/pharmacy benefit manager for eligibility and formulary adjudication and the prescription should then be forwarded to the pharmacy. The physician must have the ability to communicate with the PBM, payer and pharmacy to provide further information on the patient if necessary, such as whether the patient has failed previous therapy, has a condition or allergy which makes the "preferred" drug an unacceptable alternative, etc. In addition, handwritten signatures should not be required, even for prescriptions of controlled substances. Whatever the scenario, the physician should never have to leave the e-prescribing environment to complete a prescription.

Evolution and Implementation of an Electronic Prescription Drug Program

The AMA recognizes the ambitious time frame mandated by MMA for CMS to implement the e-prescribing standards and the many standards that must be incorporated into an effective electronic prescription drug program. However, the AMA cautions against CMS adopting foundation standards without testing them in the e-prescribing environment.

Even though there may be adequate industry experience with a current standard in a particular environment, it is not certain how the use of the standard will work for e-prescribing. Although it is understandable that CMS would want to immediately adopt a few standards that have been independently tested, merely placing together standards in piecemeal fashion without testing them in the context of the "whole process" may lead to new problems that were not before seen or anticipated. CMS should not think in terms of standards that can be incrementally pieced together to make a "whole," but rather in terms of a whole system that is comprised of standards that work together and each add value to the whole. A "roadmap" of the complex e-prescribing environment should be developed first, and the component standards should then be identified, considered and tested.

Testing should include feedback on the level of acceptance from physicians and other prescribers in addition to feedback on usability, value and functionality. Without careful and deliberative standards development, there will not be widespread adoption and achievement of the promise of e-prescribing - improved efficiency, patient safety and health care quality. Pilot testing can also help determine appropriate financial models for funding the acquisition of technology, training and support for electronic prescribing in various clinical settings.

For these reasons, **the AMA believes that pilot projects should be conducted for all proposed e-prescribing standards in order to ensure that all of the standards will work seamlessly in multiple similar and dissimilar environments**. In addition, the pilot projects should address workflow issues and establish business rules in order to minimize potential burdens on physicians.

The AMA supports a true private sector approach to standards development for e-prescribing, with the federal government participating in the standards development process. However, we urge that the maintenance and modifications to the standards not get hindered by an extensive rule-making process similar to what has been experienced with the HIPAA administrative transactions standards. All vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and any interested party should be eligible to submit proposals for additions and modifications. In addition, a panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should be responsible for maintaining the vocabularies. Ultimately, the AMA agrees with CMS that any final standards should include only those standards that are accredited by the American National Standards Institute (ANSI). It may not be necessary for all the vocabulary developers to be ANSI accredited, however the organization maintaining the code sets should ensure continuity and efficient updating of the standard over time.

Finally, the AMA urges CMS to consider implementation of the e-prescribing standards in phases rather than requiring implementation of the entire set of standards by a single date. The implementation dates could be staggered by either function or by entity, or both.

Electronic Prescription Drug Program and HIPAA Standards

With respect to adoption of HIPAA standards, we suggest that CMS adopt minimal version levels of the standards, depend on existing standards development organizations processes for newer versions, and permit health care organizations to use newer versions provided there is backward compatibility. We agree with the Workgroup on Electronic Data Interchange (WEDI) that NCVHS should hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS should then recommend such changes to CMS. If NCVHS considers the change to be substantive, CMS should issue a proposed rule within 90 days. If the change is not substantive, it should waive a formal rulemaking and comment period.

Procedures should be designed to permit the changing needs of HIPAA and e-prescribing to be met but also ensure that such modifications to standards do not result in multiple standards. Again, the AMA recommends consideration of implementation in phases rather than requiring implementation of all standards by a single date.

With respect to privacy and security in general, the AMA believes that the e-prescribing final rule should apply the HIPAA Privacy and Security Rules to all systems for e-prescribing. However, the pilot testing should be designed to first identify any privacy issues that might arise in the event some part of the Privacy Rule may need modification in the e-prescribing context. As CMS mentions in the preamble, the "minimum necessary" rule in the HIPAA Privacy Rule will apply to any disclosures of protected health information in connection with an e-prescribing standard. Yet, if a disclosure is required for compliance with a HIPAA standard, the minimum necessary requirement may be waived. However, if the e-prescribing standard is not also a HIPAA standard, minimum necessary will apply. Although the AMA believes that the "minimum necessary" rule in the HIPAA Privacy Rule is an important privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for certain information, such as a listing of a patient's drugs, or his or her medical history, are likely to be highly complex. The AMA believes that a framework for the requisite controls must be thoroughly considered and tested prior to implementation of such standards.

Standard Identifiers

The AMA recommends that the HIPAA National Provider Identifier (NPI) be the primary identifier for prescribers and dispensers. However, the required date for use of NPI in transactions in this NPRM must not be accelerated before the required date for use of NPI in HIPAA transactions. There must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before the NPI can be mandated. The NPRM date of January 2006 is too soon because of non-availability of these NPI system capabilities. In addition, current identifiers should be used by prescribers and

dispensers until the NPI and its system, including batch enumeration and database access, are available.

Formulary and Medication History Standards

The AMA believes that the formulary, benefit and medication history messaging standards currently being developed should be thoroughly pilot tested before any standards become final. Vendors should be encouraged to bring products to market that assist physicians to comply with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered as pharmacies and pharmacy benefit managers must have systems up and running to allow physicians to send test prescriptions that comply with new standards. Physicians must rely on their vendors to provide them with the tools necessary to comply with the electronic prescribing program.

We urge CMS to consider lessons the industry has learned from implementing the HIPAA Transactions and Code Sets rule. Implementation was severely delayed by the inability of the physicians and the provider community in general to upgrade their practice management and billing software in a timely manner. CMS had to resolve inter-governmental differences from across the Federal government in the Addendum to the Transactions and Code Sets rule. The additional time it took to resolve these differences left inadequate time for vendors to work with physicians and payers to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long, and not conducive to industry usage.

The AMA is concerned that the criteria CMS outlines for medication history standards only technically states the objectives without a more detailed roadmap for implementation. These criteria are that the standards:

- are accredited by an ANSI-accredited standards development organization.
- permit interface with multiple product, router, and POC vendors.
- provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.
- provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.

These criteria will be very difficult to accomplish and there is potential for many practical complications that will require considerable time to implement.

As mentioned previously, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for a listing of a

patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex. A framework for the requisite controls must be thoroughly considered and tested prior to implementation of the medication history standard.

The AMA is also concerned that the current industry models for retrieving prescription and medication history are developing and deficient thus far. Because patients often utilize multiple pharmacies, the prescription record at any one site is often incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but to rule out a diagnosis, and a record of the outcome is not recorded.

Proposed Standards

The AMA has a few concerns with the eligibility and benefits standard CMS proposes to adopt for inquiries between physicians and Part D sponsors. The ASC X12N 270/271 Eligibility Inquiry and Response Standard is inadequate. In the current HIPAA eligibility transaction a health plan can either give detailed benefit information or simply give a brief response: Yes-this person is eligible or No-this person is not eligible. Physicians need more detail than yes or no, and they need the information in a more consistent way.

Private industry groups, including health plans, physicians and other health care providers, are working together on a project to improve the quality of the eligibility responses to provide more information that is relevant and needed by physicians and other healthcare providers. The goal of the project is to encourage all health plans to respond to eligibility questions based on business rules established by the industry that are agreed to by health plans in concert with other key stakeholders, namely healthcare providers, vendors, and X12. This effort has just begun, but the goal is to finalize a first set of rules by December 2005. The AMA is a participant in this project and recommends that the requirement for better response information be strengthened in accordance with the findings of the outcome of the project.

The AMA believes that there should be further enhancement and testing of RxNorm as stated previously, and enhancement and testing of the National Drug File, Reference Terminology (NDF-RT) that is being developed for the Veterans Administration as a reference standard for medications to support a variety of clinical, administrative and analytical purposes. In addition, National Drug Codes (NDCs) work well for pharmacy purposes, but they are too granular for physicians to use for clinical purposes. As a result, many prescriptions today are transmitted in free-form text, resulting in re-entry and potential errors at the pharmacy, as well as lost opportunities for clinical decision support. The standards should support clinical decision making in addition to administrative tasks. Therefore, much work is still necessary in order to provide a consistent physician-level drug vocabulary.

Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT standard.

Regulatory Impact

To successfully implement voluntary electronic prescribing in the Medicare program, HHS should be fully aware of the future Medicare environment for physicians. By law, e-prescribing standards must be in place by April 1, 2009. At the same time, CMS actuaries predict five percent annual payment reductions for physicians for six years, starting in 2006. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. This means that by 2012, physicians will be paid about 26% less than in 2005, while practice costs will have increased significantly.

In this financial environment it will be extremely difficult for physicians to allocate the resources necessary to invest in new technologies. The AMA believes e-prescribing offers significant potential benefits to physicians and their patients. But investments in e-prescribing hardware and software may be difficult given the dramatic reimbursement reductions forecast in Medicare. The AMA urges CMS to eliminate the flawed physician payment formula, and to fund development of analysis and educational documentation making the financial and clinical case for e-prescribing investments by physicians.

Given the limited financial resources for many physician practices, the AMA appreciates that e-prescribing is currently voluntary. For widespread and successful adoption of e-prescribing in the near future, we underscore the need for an irrefutable, tangible benefit to patients and physicians. To this end, careful and deliberative standards development is critical to achieving the ultimate promise of e-prescribing - improved efficiency, patient safety and health care quality.

In conclusion, the AMA would like to thank CMS for the opportunity to submit these comments. We look forward to additional CMS rules on the e-prescribing and pilot projects for 2006. If you have any questions regarding our comments, please do not hesitate to contact Anders Gilberg at (202) 789-4688.

Sincerely,

Michael D. Maves, MD, MBA

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Virginia L. Bartlett
Chief Privacy/Security Officer
U.S. Operations

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April 5, 2005

Dr. Mark McClellan
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Attention: CMS-0011-P
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Baltimore, MD 21244-8014

Dear Dr. McClellan,

IMS Health, the world's premier source of prescription intelligence, applauds the Centers for Medicare and Medicaid Services (and the advisory body, the National Committee on Vital and Health Statistics) for its work to advance the standard-setting process. As IMS Chief Privacy/Security Officer, I am pleased to offer comments on the Medicare Electronic Prescribing Proposed Rule (Fed Register Vol. 70, No. 23, Friday, February 4, 2005).

A demonstrated leader in precision statistical methodologies and accurate reporting for 50 years, IMS delivers a total picture of prescription activity across channels, locations, drug types and specialties. As a trusted partner to pharmaceutical and healthcare companies worldwide, we believe that patient information is among the most sensitive of all data and must be protected. More detailed information on IMS is attached.

In response to the CMS request for comments, IMS provides recommendations on four areas we believe will facilitate electronic prescribing. These specific suggestions are:

- Establish HIPAA Privacy as a foundation "standard";
- Develop a workable approach to preemption;
- Make inclusion of the National Provider Identifier optional until there is sufficient industry experience and a system for authentication and access; and
- Do no harm to statistical integrity during the uptake period.

IMS is available to provide assistance and further information on e-prescribing, health data privacy and standards development as needed. Thank you for your consideration of these comments.

Sincerely,

Virginia Bartlett
Chief Privacy/Security Office

Overview of Comments on the Proposed Medicare Electronic Prescribing Rule

Passage of the Medicare Modernization Act (MMA) codified many key changes in the health care system, including an ambitious agenda for uptake of electronic prescribing within the Medicare program. Understood within the larger context of a National Health Information Network, we view electronic prescribing as a valuable tool for improving patient safety and cutting costs. IMS HEALTH (IMS) has engaged in policymaking on HIPAA, electronic prescribing and electronic health care, and work on the National Health Information Network by monitoring the National Committee on Vital and Health Statistics (NCVHS), meeting with key policymakers on Capitol Hill and within the Department of Health and Human Services, participating in relevant coalitions in Washington, and submitting official filings on related topics (including a response to the Office of the National Coordinator for Health Information Technology's Request for Information on the NHIN and interoperability).

IMS identifies the following components of an effective implementation of electronic prescribing and realized success of the agency's electronic prescribing objectives for patient safety and cost savings. For electronic prescribing to succeed, we believe electronic prescribing must:

1. Encourage prescriber adoption and meet state requirements for prescription drug dispensing;
2. Be interoperable with existing marketplace analytics to assure broadest acceptance of the standards;
3. Facilitate the tracking of drug utilization, therapy adherence and quality systems in order to improve patient safety;
4. Maintain patient confidence about safety, security, and value of the system; and
5. Further the goals of the National Health Information Network.

Our comments analyze electronic prescribing success within this framework.

Patient Privacy: HIPAA Should Be A Foundation Standard

Our overarching view of both electronic prescribing and electronic health care is that attention must be paid to patient privacy, interoperability and the integrity of data systems and statistics that are key to advancing the President's goal of electronic health care, improvements in patient safety, and cost savings.

While IMS Health supports the standard setting underway as a means to motivate adoption of electronic health care, we believe acceptance may be more rapidly achieved by including as a foundation standard existing patient privacy and security protections. We believe HIPAA Privacy & Security Rules should be guiding principles for the implementation of electronic prescribing.

Recognizing and preserving the HIPAA Privacy Rule is essential to the success of e-prescribing. It is also an area that meets the adequate market experience baseline for a foundation standard as called out in the e-prescribing proposed rule. While the MMA does not require that physicians gain a patient's approval to electronically prescribe, we anticipate that as electronic prescribing, and electronic health generally, achieve market uptake, patient confidence – and willingness to participate – will be key to success. By adopting a known patient privacy standard at the outset of standard-setting, CMS may improve patient confidence in an electronic health system. A recent study found that Americans are divided on whether the benefits of electronic health care (patient safety, quality of care, etc) outweigh the risk (unauthorized disclosures of health information)[1]. Reinforcing the applicability of HIPAA as a foundation standard may help allay some of these concerns.

By applying HIPAA as a foundation standard to e-prescribing, the Department will also accomplish the baseline protections it will need to generate statistics and comparative value information from the dispensing activity that occurs inside an e-prescribing network. In particular, IMS highlights the section of the HIPAA Privacy Rule that contains the industry standard for the de-identification of patient data. Companies such as IMS already de-identify data successfully as standard practice. With HIPAA as a guide, the industry can create and release research statistics and link their own data to other types of health outcomes information. IMS believes this standard for de-identified data is an appropriate solution as CMS looks to analytics on dispensing activity, drug utilization, and therapeutic effectiveness as well as insight to therapy progression in treatment of specific diseases such as Parkinson's, analysis of concomitant medications and identification of those that might be contra-indicated in combination.

Acceptance of the HIPAA baseline is essential for anyone, including patient safety advocates, the FDA and medical researchers, who monitors prescribing activities and the drug pipeline for regulatory and other public good purposes. Prescriptions written in a new e-prescribing network may be for new patients or by physicians who have switched from paper prescriptions to electronic prescriptions. In either case, visibility is necessary to ensure valid public good results. By applying the HIPAA rules for access, CMS can capture this activity and assure statistical integrity during the uptake period.

The NCVHS aptly described the importance of privacy protections to the Secretary by stating, "the main privacy issue that needs to be resolved in an e-prescribing regulation is what rights consumers should have to limit access to their prescription records." While patient identifiable data is necessary for certain basic prescribing functions (ie: filling and claims processing), de-identifying patient data provides a means of using data for key research and patient safety and quality tracking while providing patients with the highest level of protection. We refer CMS to Dr. Alan Westin's

[1] Professor Alan Westin testifying at the National Committee of Vital and Health Statistics; February, 23, 2005.

(Professor of Public Law and Government at Columbia University) recommendation to the NCVHS that among other privacy considerations, a privacy working group should "identify and test anonymization techniques to enable both advanced medical research and data-analysis services."[2] Anonymization, or de-identification, promoted in HIPAA and the Privacy Rule for research and data analytics purposes, should be a model for data security in an electronic environment – especially at a time when security breaches and identity theft are at the forefront of public debate.

In summary, IMS urges that CMS establish the HIPAA Privacy and Security Rule as a baseline foundation standard for e-prescribing. Action taken now will facilitate confidence, establish certainty, and ensure patient acceptance of a known standard. It will also establish a means for CMS to maintain statistical integrity and evolve the value of e-prescribing.

Preemption

"CMS invites comments on the scope of preemption."

It is no surprise to see a continuation of debate on state preemption given either the intensity of negotiations during HIPAA deliberations or the much-debated use of "and" linking the two criteria for exemption of state law within the MMA.[3] If CMS chooses to stay with the current interpretation of preemption, we note the importance of investing in information solutions to help negotiate differences between federal and state law. The legal efforts involved with determining where state and federal laws intersect and diverge are extremely costly and time consuming and may well serve as yet another reason physicians cite for opting not to prescribe electronically. Thus, CMS should engage in discussions with industry on how best to bridge (using reference files) or "crosswalk" between information fields required to meet state and federal law. Doing so will diminish some of the legal and technological barriers to physician uptake.

Such crosswalks currently exist and are successful due to economies of scale (that is, large quantities of prescribing information that demand crosswalks between state and federal law enable a more cost-efficient means of creating and executing the crosswalks than if there were a fewer amount of prescriptions to consider). For example, IMS builds crosswalks between the federal and state Medicaid prescription drug rebate rules for pharmaceutical manufacturers. Without these information solutions, our clients would have enormous complexities involved with achieving a single rebate calculation in the

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[2] Dr. Westin's full testimony to the NCVHS is available at www.pandab.org and www.ncvhs.hhs.gov, see testimony from February 23, 2005. Dr. Westin expands on the recommendation: "From the start, EMR systems need to develop the identification filters and maskers that will enable researchers and data analysts to access anonymized health records sources. Surveys have shown the public to be very nervous about researcher access to their medical records, and this calls for powerful anonymizing processes to be installed, verified, and communicated to the public from the start, not retrofitted."

[3] Relevant section of the Medicare Modernization Act cited in the Proposed Rule on Electronic Prescribing: *Federal Register,* Vol. 70, No, 23: February 4, 2005. 6258.

context of state and federal laws. Our crosswalks are a cost-efficient way of achieving a single calculation. As a company that performs this service, we know that every change in regulations adds cost and confusion to meeting state and federal law. For example, under the new MMA, we will now need to account for the transition of dual eligibles from Medicaid to Medicare. That said, crosswalks that exist on a large scale (ie: broader than a single company or case) are a cost-efficient way of negotiating regulatory differences and changes.

To this end, IMS urges CMS to define crosswalks to state law and test such information solutions in pilot testing. We also encourage the Secretary to preempt state law for the purposes of pilot testing. Without doing so, pilot testing in certain states may be unable to occur or be ineffective.

National Provider Identifier

> *We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliances dates alternatives to the NPI, particularly in the short term and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process...NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispenser and the NCPDP HCIdea for identifying prescribers...We are looking at various options for an alternate identifier(s) , including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this as well..."*

IMS does not believe the NPI is an adequate prescriber identifier for electronic prescribing use at this point in time. We believe there are numerous unresolved short and long term problems with the identifier that need to be resolved before the industry can achieve the experience necessary for use.

In the short-term, the NPI will not be available widely in 2006, it has never been tested in industry in any capacity, and it fails to meet CMS' definition for a foundation standard for e-prescribing. Concerns that require further experience include: use of key information fields, crosswalks between the NPI and other industry identifiers, and failure to link the identifier to physical location or mandate that there be a single identifier per prescriber. Resolution of these issues is critical to the success of the NPI as an identifier and also to e-prescribing should CMS determine the NPI appropriate for use in the future.

The limited use of key information fields is inadequate. With only one location field[4] and a lack of validation during the enumeration process[5], there is very little means for users of the NPI to authenticate the NPI against other records and thus adequately protect against fraud and abuse – already a prescribing concern. While we understand that the Final Rule on the National Provider Identifier does give the Secretary of HHS the

[4] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3450

[5] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3446

authority to use the NPI for various purposes[6], we note for CMS that the decision not to validate physician-submitted information (in order to keep enumeration costs down) renders the NPI less valuable than other commonly used physician-identifiers. As another example, we would bring to CMS' attention that an NPI is not mandatory for all individual prescribers. If an individual does not require a unique NPI for billing, or is not a covered entity under HIPAA, then they need not apply for one.[7] This leaves a potentially disruptive gap for the processing of e-prescribing transactions and normal prescription claims processing, where an identifier is needed for all prescribers.

We urge CMS to thoughtfully consider the characteristics of the NPI that, while sufficient for claims processing, are not adequate for prescribing purposes. Such a consideration would look at the NPI's inability to ensure accuracy, credibility, and usability in a prescribing environment.

Therefore, it is our recommendation that in the short-term, CMS permit use of existing, currently used identifiers for electronic prescribing purposes. Other identifiers, including the SureScripts Prescriber ID (SPI), the DEA number, medical license numbers, and other proprietary identifiers are currently used widely in the industry for prescribing purposes and we recommend continued use until an identifier can be deemed sufficiently tested and workable for all industry partners. For example, after a period of use and when CMS resolves problems (such as validation and mandatory use for all individual prescribers) the NPI potentially could be an appropriate identifier.

In the event that the NPI is used in electronic prescribing, we urge CMS to ensure that the data dissemination strategy recognizes the importance of crosswalking between the NPI and legacy identifiers. Failure to do so will compromise the quality of health care data tracking, including the prescription drug monitoring that IMS does on behalf of both the government and the private sector. More importantly to CMS, if there are not accurate crosswalks available for all stakeholders in prescription claims processing, the new identifier will not be wholly adopted in that arena, and all the existing identifiers will continue to be used along with the NPI. Administration simplification therefore depends on creation and widespread availability of crosswalks. To this end, CMS should make the NPS reference files available so that data analysis may continue unhampered. This access must be permitted beyond HIPAA covered-entities. We recommend an approach that allows for file use to those who certify their compliance with relevant HIPAA regulations, including the Security Rule, in order to ensure appropriate use of the information.

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[6] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3449

[7] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3438

Based on these concerns, IMS opposes adoption of the NPI as part of the e-prescribing rules until there the aforementioned concerns are appropriately addressed. In short, IMS urges the Secretary to in the final rule to:

1. Validate the continued use of authentication crosswalks such as the SureSpripts, DEA and Medical Education (issued by state license board) number at least until 2010;
2. Assert that within the e-prescribing network identifiers must be assigned for all individual prescribers; and
3. Mandate that physical location be tied to that prescriber.

Additionally, we do not view HCIdea as an adequate interim solution to the NPI. HCIdea is not currently widely used in the industry, does not meet CMS criteria for "adequate industry experience,"[8] and does not meet the criteria outline above.

Other Comments: Interoperability Testing Is Needed for Metrics

IMS believes the most efficient way to achieve the dual goals of e-prescribing and the NHIN is to facilitate, not replace, industry ability to generate metrics about prescription activity. Today, data that analyzes prescribing practices is key to many public health efforts, including tracking prescribing patterns, drug safety recalls, understanding drug utilization, treatment patterns and therapy progress, resource utilization, market trends and usage. In order to continue these essential functions, and, indeed, to facilitate the patient safety and quality tracking promise of electronic prescribing, CMS must ensure continued access to data. Continued access will prevent any inconsistencies or holds on the data flow to currently useful and thriving data tracking and analysis.

Two examples in which access to and use of de-identified data facilitate key public health functions while protecting patient privacy are:

1. In the marketplace today, the FDA requires that pharmaceutical manufacturers self-monitor and report new product market introductions to ensure appropriate prescribing and use. This is most frequently accomplished through use of statistics on dispensed prescriptions. Visibility to the data dispensed within an e-prescribing network is therefore essential to manufacturers compliance and patient safety.
2. Uses of prescription drug data by indication – where the patient is de-identified – can help to identify under-treated conditions, managed care management techniques and proper use of drugs for specific age groups, (e.g. antidepressants in children)

[8] Proposed Rule on Electronic Prescribing: *Federal Register,* Vol 70, No, 23: February 4, 2005. 6261.

These examples, each representing permissible activities under HIPAA, are also necessary for a successful e-prescribing network, EMR and NHIN. Given the critical importance of this issue, IMS strongly recommends that statistical interoperability be tested in the pilot projects and that there be two goals: 1) to assure integrity; 2) to develop a comparative base about in-network dispensing for the marketplace. Specific issues such as the impact of additional and conflicting points of collection can also be included in test requirements.

Conclusion

IMS appreciates the opportunity to offer these comments on this important initiative and hopes CMS will:

- Protect patient privacy and research by recognizing the HIPAA Privacy and Security Rules as a foundation standard.
- Allow for continued access to and use of de-identified patient data as set forth in the Privacy Rule;
- Explore the role information solutions can play in helping stakeholders meet requirements of state and federal laws, should the narrow interpretation of preemption remain;
- Consider the characteristics of the NPI that make it an insufficient identifier for prescribing purposes and recommend continued use of multiple identifiers for prescribing purpose; and
- Include statistical interoperability as a component of pilot testing to ensure ongoing data integrity.

We look forward to the next phase of electronic prescribing rulemaking and engaging in forthcoming pilot projects.

Attachment:
Background on IMS Health

IMS HEALTH is the world's leading provider of information, research, and analysis to the pharmaceutical and health care industry with data collection activities in over 100 countries. In the United States alone, the company collects information from pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes over 375 million de-identified records each month.

IMS HEALTH's business includes tracking patterns of diseases, treatments, outcomes, prescriptions, and sales of pharmaceutical products. The company receives and analyzes de-identified data. Using this data, we are able to assist the medical, scientific, and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. The company's databases of de-identified prescription drug transactions are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, and assessment of drug utilization patterns (i.e., on- and off-label uses and regional variations in prescribing behavior).

IMS HEALTH recognizes the sensitivity of health information and has operated with long-standing comprehensive practices to protect the privacy of individuals and preserve the confidentiality of the information we collect. These practices include: requiring that transaction data be de-identified prior to being sent to IMS HEALTH; screening records before acceptance to ensure that they are de-identified; tightly controlling access to data; requiring informed patient consent before collecting any individually identifiable information; restricting use of information; routinely auditing information practices; and entering into confidentiality agreements with data sources, employees, and clients.

#19

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

April 5, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P
P.O. Box 8014,
Baltimore, MD 21244-8014

Re: Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule

Dear Administrator McClellan:

The Medical Group Management Association (MGMA) appreciates the opportunity to comment on the proposed rule on e-prescribing. MGMA is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

General Comments

As the federal government and the health care industry move toward adoption of standards for electronic prescribing, the following issues should be considered:

- E-prescribing Standards Should be Flexible and Scalable – From the physician perspective, standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. The final standards must be both flexible and scalable to encourage adoption by both small and large health care organizations and low- to high-volume prescribing physician specialties. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency and integration with existing practice management software and electronic medical record systems when making an investment.

- E-prescribing Standards Should not Impose Undue Burdens on Providers – In these challenging economic times, with decreasing reimbursement and increasing practice expenses, it is critical that the Centers for Medicare and Medicaid Services (CMS) craft a final rule that does impose undue financial burdens on physician practices. Furthermore, e-prescribing systems should be designed in such a way that clinicians are able to utilize this technology in a time-efficient manner. Clinicians may be discouraged from adopting the technology if it takes them significantly more time to write a prescription electronically than on paper.

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- Ensure System Interoperability – In order for an electronic prescribing system in a medical practice to communicate effectively and securely and share patient data with other medical practices, hospitals and pharmacies, they all must speak the same "language." E-health standards developed by either the federal government or industry must have the ability to be utilized by multiple stakeholders using a myriad of computer systems. At the same time, "interoperability" should also include the ability for an electronic prescribing system to seamlessly interact with other clinical and administrative systems in the practice.

- Promote the Security and Privacy of Patient Data – Patients are more concerned than ever about maintaining the security and privacy of their health information. At the same time, providers are embracing the new standards in these areas as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). E-prescribing must maintain these HIPAA standards as part of its core operating features.

- Establish a Quantifiable Return on Investment – For many group practices, the economics of investing in e-prescribing and other health information technology is simply not evident. In an environment of significant scheduled Medicare reimbursement cuts, sharply rising malpractice premiums and ever-increasing practice expenses, many practices are concerned that moving to an electronic information system will not be financially beneficial. MGMA recommends that CMS establish a quantifiable return on investment through survey research and a comprehensive cost/benefit analysis for all sizes of physician practices.

- Incentives for Providers – While medical practices typically absorb the cost of purchasing the health information technology necessary for electronic prescribing many of the benefits accrue to others in the system. MGMA believes there should be a "realigning" of these incentives by promoting appropriate public and commercial reimbursement programs. MGMA has supported the concept of a federal program of tax credits for physician investments in health technology that could serve as a significant incentive. Additionally, a federally guaranteed loan fund for physician health technology investments, coupled with loan forgiveness for service to medically underserved populations, could also be a stimulus.

- Technology Savings Accounts – The federal government should also explore innovative methods of assisting physician practices to acquire health information technology such as electronic prescribing. Technology Savings Accounts (TSAs) would provide a reduced level of taxation for funds designated for practice health information technology. A TSA would be a special account owned by a group practice where contributions to the account pay for current and future qualified health information technology expenses including electronic prescribing software and hardware. A TSA savings product offers a different way for group practices to pay for their health information technology expenses. TSAs could enable group practices to pay for current expenses and save for future qualified health information technology expenses on a tax-free basis. Unspent account balances would accumulate and accrue interest.

- Stark Regulation Safe Harbor – There are clear legal barriers to the adoption of health technology solutions in medical groups. Anti-kickback and self-referral concerns prevent some health care organizations from offering free or discounted technology to medical practices. MGMA has advocated for government approval of legal protections, such as safe harbors and regulatory exceptions, to facilitate health technology implementation. We congratulate the CMS recent important step in this direction through its creation of a health technology safe harbor in the physician self-referral phase II interim final rule (CMS-1810-IFC; 59 Fed Reg 16054).

- Consultation with the Physician Practice Community – Physician practices must play an integral role the development and deployment of any standardized e-prescribing system. Since the vast majority of all health care is delivered in medical practices, the success or failure of these initiatives will depend heavily upon physician acceptance of this new technology. MGMA encourages CMS to continue its outreach to this community to ensure that the requirements and concerns of physicians are addressed.

- Patient and Provider Outreach – The successful adoption of e-prescribing will depend, in part, on the ability of the federal government and the industry to encourage both providers and pharmacies to understand and support the system. It is imperative that these two critical stakeholders are well educated as to the systems' capabilities as well as its security and privacy components. In addition, MGMA recommends that CMS work with the appropriate provider and consumer associations as well as the popular media to deliver a consistent message to patients on this important change in the health care system.

- Work with the industry to expand this regulation beyond Medicare Part D – This regulation is expected to enhance patient safety and efficiency for the Medicare Part D program. CMS should expand the use of this standard beyond Medicare and MGMA is hopeful that a successful implementation of this regulation will trigger adoption of these standards by the private sector. MGMA encourages CMS to facilitate this expansion by working with the private sector to exchange data and experiences as well as develop educational materials that will assist stakeholders move forward with e-prescribing.

- Learn from the HIPAA Experience – The protracted nature of HIPAA Transactions and Code Sets implementation process suggests that the federal government's e-health regulatory process must be modified. MGMA calls on the government to stagger implementation dates, thus providing health plans and clearinghouses time to upgrade and test systems before provider implementation takes effect. While piloting is not needed to establish the applicability of the core function standards, piloting of the entire e-prescribing standard should be completed prior to full national implementation in order to identify and correct problems.

Specific Comments on the Notice of Proposed Rule Making

Issue: **State Preemption (70 Federal Register No. 23 Feb. 4, 2005 page 6258)**

We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.

Response:

MGMA believes that the proposed rule adopts a very narrow interpretation of federal preemption. The rule appears to limit preemption to only those Part D beneficiaries enrolled at the time the prescription is issued, rather than all Medicare beneficiaries. We also have a concern that Medicare beneficiaries may receive drug coverage from multiple sources. Yet, the rule seems to limit preemption to only those prescriptions actually covered by Part D. MGMA recommends that CMS adopt an interpretation providing that federal law broadly preempts any state laws that are contrary to

or that stand as an obstacle to the objectives of the federal government in creating the e-prescribing standards. We believe that this interpretation is consistent with the settled view of preemption and statutory language. MGMA also suggests to CMS that the preemption standard apply to any prescription issued to any beneficiary eligible for Part D coverage.

Issue: **Current E-prescribing Environment (70 Fed Reg 6260)**

The use of e-prescribing shows promise for improving Medicare operations by creating efficiencies in the administration of the Part D drug benefit, by decreasing costs in facilitating patient eligibility checks, promoting generic drug use, and creating timely interface with formularies. This also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

Response:

MGMA believes that e-prescribing will help to deliver relevant patient information and clinical knowledge to the clinician and this will reduce the likelihood of a faulty prescription. In addition, e-prescribing holds the promise of improved administrative efficiencies. Presenting all relevant information to the clinician at the time of prescribing may help streamline the entire prescribing process. Relying solely on downstream inspection to manage quality is inefficient because of the extra work required. By some accounts, the nation's three billion prescriptions generate approximately 150 million clarification phone calls every year. This means that roughly five percent of prescriptions are somehow incompletely specified or unclear, and need to be reworked.

Early experience supports the view that electronic prescribing – by shifting the error-inspection process to the point of prescribing – reduces callback volume and improves efficiency. In fact, most clinics that successfully deploy electronic prescribing applications note a dramatic decrease in prescription clarification calls. Moreover, those callbacks that still occur can usually be processed more efficiently because of the streamlined message-handling capabilities that often come with electronic prescribing, coupled with elimination of the need to pull (and re-file) paper charts every time a pharmacist or patient calls with a question or concern about a prescription. This reduction in chart pulls is one of the unheralded beneficial side effects of electronic prescribing and has major cost-savings implications, particularly for larger practices. Even in small practices, however, there is still significant time lost looking for charts that have not been filed and are in multiple locations around the office, waiting for various processes to be completed.

Issue: **Evolution of Standards (70 Fed Reg 6261)**

We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.

Response:

MGMA supports the creation of e-prescribing standards as needed by the private sector through ANSI accredited standards developing organizations, with federal government participation in the standards development process. We urge that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to that experienced with the HIPAA Transactions and Code Set standards. In addition, MGMA recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and

any interested party should be eligible to submit proposals for additions and modifications. A responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should maintain these vocabularies.

Issue: **Criteria to Assess "Adequate Industry Experience" (70 Fed Reg 6261)**

We propose to use the following criteria to assess adequate industry experience (with transaction standards), based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria:

- *The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.*

- *The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

- *The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.*

Response:

MGMA agrees with this approach to determine if a standard is deemed to have had "adequate industry experience." We would like to emphasize the importance of the final bullet, that the standard be recognized by key industry stakeholders, as this is critical to ensure that the standard has been used in clinical settings and found to be acceptable. In particular, we encourage CMS to continue its outreach to the provider community to ensure that any futures, standards take into account the requirement of clinicians.

Issue: **Drug orders for fill status notification (70 Fed Reg 6262)**

NCVHS Standards Recommendations – HHS Should :include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. Standard in the NPRM: No.

Response:

MGMA is disappointed that CMS decided not to include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. This standard has the potential of significantly improving the health of Medicare beneficiaries. With some industry sources estimating that up to 40 percent of written prescriptions are never filled by the patient, it is clear that many patient conditions are not easily monitored by physicians.

Failure to refill medications at a pharmacy or renew at the clinician's office in a timely fashion can and does lead to adverse events due to exacerbations of the condition. This is a significant problem particularly for persons who have difficulty affording their prescriptions. Renewing prescriptions in a timely fashion may not be a high priority, especially for drugs that treat relatively asymptomatic

chronic conditions. Lack of patient compliance with prescribed medications can also lead to similar adverse events. With electronic prescribing systems leading to better tracking of a patient's drug regimen, it is possible to know when renewals of regularly scheduled medications are likely to come due, assuming proper patient compliance. Systems can send out reminders to patients and clinicians, advising of an upcoming renewal or refill time and even offering one-click renewal transactions. These reminders should have a positive impact on actual compliance.

It would be easy for elderly Medicare beneficiaries, who may be taking multiple prescription drugs, to miss filling an important prescription. Thus, prescription fill status could be an important device allowing clinicians to better monitor chronic care illness, potentially lowering overall health costs by preventing hospitalizations due to improper drug usage. In addition, fill status would potentially be an important patient safety, patient satisfaction and quality measurement. We are hopeful CMS will consider including this function in later standards.

Issue: **Version Control (70 Fed Reg 6267)**

If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the Federal Register of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.

Response:

MGMA recommends that HHS (i) adopt minimal version levels of the standards; (ii) depend on existing standards developing organization (SDO) enhancement processes for newer versions; and (iii) permits health care organizations to use newer versions provided there is backward compatibility. MGMA recommends that the National Committee on Vital Health Statistics (NCVHS) hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS would recommend such updates to HHS. If NCVHS considers the change to be substantive, as described on 70 Fed Reg 6267 above, HHS would issue a NPRM within 90 days. If the change is deemed not to be substantive, it would waive notice and comment.

MGMA is concerned about any possible divergence between a HIPAA standard transactions and the same e-prescribing transaction, such as the ASC X12N 270/271 eligibility inquiry. MGMA recommends that procedures be designed to permit the changing needs of HIPAA and e-prescribing to be met but that such modifications to standards do not result in multiple standards. MGMA also recommends consideration of implementation phases rather than requiring all transactions by a single date.

Issue: **National Provider Identifier (70 Fed Reg 6263)**

We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.

NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.

Response:

MGMA is a strong supporter of administrative simplification and believes that the national provider identifier (NPI) is an important step in streamlining health care transactions. The NPI should be the primary identifier for all prescribers and dispensers utilizing e-prescribing. MGMA recommends that current identifiers not be required to be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access are available.

In addition, while MGMA recommends that the required date for use of the NPI in transactions in this NPRM not be sooner than the required date for use of the NPI in HIPAA transactions, we strongly urge CMS to move forward with the NPI enumeration process. E-prescribing will be greatly facilitated with a standard provider identifier. We recommend that CMS work with providers and other stakeholders to develop an NPI implementation plan that results in rapid and successful adoption of this important new standard.

Issue: **Formulary and Medications Standards (70 Fed Reg 6263)**

We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:

Response:

In order to facilitate a successful implementation, MGMA recommends that the formulary, benefit and medication history messaging standards should be thoroughly pilot-tested prior to the release of a final rule. Vendors should be factored into the regulations and encouraged to bring products to market that assist physicians in complying with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered, as pharmacies and pharmacy benefit managers must have systems up and running to allow physicians to send test prescriptions that comply with new standards. Physicians must rely on their vendors to provide the tools necessary to comply with the electronic prescribing program. Strong government leadership will be critical to rapid and seamless conversion to the new standard.

MGMA urges that HHS make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of HIPAA. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had the most difficult task of trying to resolve inter-agency differences from across the federal government in the Addendum to the Electronic Transactions and Code Sets rule (citation). The additional time to resolve these differences left inadequate time for the various vendors to work with their provider and payer customers to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long and not conducive to industry usage.

Issue: **Medication History (70 Fed Reg 6263)**

We propose the following critical characteristics for medication history standards:

- *The standards are accredited by an ANSI-accredited standards development organization.*
- *The standards permit interface with multiple product, router, and POC vendors.*
- *The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*
- *The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.*

Response:

MGMA recommends private sector development and maintenance of standards and modifications and enhancements to standards not be hindered by extensive rule-making processes. We are concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the HIPAA Privacy rule is powerful privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for a listing of a patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex.

MGMA is also concerned that the current models for retrieving prescription and medical history is daunting. For example, patients often utilize multiple pharmacies—often making the prescription record at any one site incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but to rule out a diagnosis, and a record of the outcome is not recorded.

Issue: **Proposed Standards (70 Fed Reg 6264)**

We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the

strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:

- *The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

- *The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

- *The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

Response:

MGMA agrees with moving forward with these "foundation" standards. It is clear that the industry has already adopted these standards and that they meet the basic needs of the industry. However, MGMA encourages moving to new standard versions as soon as practical, in particular, moving to the new versions of the ASC X12N 270/271 and 278. MGMA also agrees that these foundation standards do not need to be piloted to determine their applicability to the e-prescribing regulation. However, as noted above, we encourage CMS to initiate a comprehensive pilot of the entire standard prior to implementation.

For future additions to the standard, MGMA recommends pilot projects in order to prove the standards not named as foundation standards will work in multiple provider and pharmacy environments. As well, pilot projects should address workflow issues and establish the business rules in order not to impose undue burden on physicians and pharmacies. MGMA recommends that demonstration pilots show achievable financial models for appropriately funding the acquisition of technology, training and support for electronic prescribing in various clinical settings. Pilot projects may also be required for any standard already demonstrated but being proposed for use in new circumstances.

Issue: **Strategy for Phasing in Implementation of an Electronic Prescription Drug Program (70 Fed Reg 6264)**

In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the

following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking.

Response:

MGMA agrees with this phased in approach to the e-prescribing standards. It is important to have the foundation standards adopted quickly by the industry to ensure that the benefits of e-prescribing are achieved in a timely manner. It is also important to move forward with the additional standards with all deliberate speed, with the caveat that these standards be properly vetted through the appropriate standards organizations and piloted when there is insufficient industry experience. MGMA encourages CMS to institute a comprehensive industry outreach program, focused on the provider community. Each release of a new e-prescribing standard should be prefaced with an educational program to explain the new standard and how it should best be implemented.

Issue: **Eligibility (70 Fed Reg 6266)**

We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors...

Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.

We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.

Response:

For eligibility inquiry and response, MGMA supports the ASC X12N 270/271 for the patient eligibility and benefits inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA. However, as much as this transaction has the capability of significant return on investment by reducing the cost for both medical practices and health plans to verify patient eligibility, in reality, much of the value of this transaction has not been realized. Medical practices report that health plans are simply responding with a "yes" or "no" when queried. While this is permitted under HIPAA, this minimum level of response necessitates the practice use the telephone to ascertain other eligibility information from the health plan – thus incurring significant costs to their organization and for the health plan.

We are hopeful that a recent industry initiative may assist in providing additional electronic eligibility and benefits information to medical practices. MGMA is working with Council for Affordable Quality Healthcare (CAQH) to improve the quality of 271 eligibility responses from health plans in order to provide more information that is relevant and needed by physicians and other healthcare providers. The CAQH is seeking to define operating rules that health plans will voluntarily adopt, providing information as to whether the patient is covered and guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. MGMA recommends that CMS consider modifying the 270/271 to include these operating rules as required data elements in future versions of

the standard.

Issue: **Coordinate Update Process when e-prescribing and HIPAA Standards are the Same (70 Fed Reg 6267)**

We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 16 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

Response:

MGMA recommends that CMS not approach standards that fall within the purview of both e-prescribing and HIPAA differently. CMS should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

Issue: **Regulatory Impact Analysis (70 Fed Reg 6268)**

We invite public comment on our expectations for prescriber participation.

Response:

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2011. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40 percent less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to help the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment, it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless it provides an irrefutable, tangible benefit to their patients and practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of e-prescribing's promise of improved efficiency, patient safety and health care quality. MGMA believes that e-prescribing offers significant financial and other benefit potential to providers. However, this observation may not appear compelling to many providers in the financial environment between now and 2011. MGMA recommends that CMS fund the development, analysis and educational documentation making the financial case for providers to implement health information technology.

Issue: **Standards Development Approach (70 Fed Reg 6264)**

While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that

are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.

Response:

MGMA believes interoperability with many clinical terms is very important. For example, some terms may be used differently in a hospital setting than an ambulatory environment. Final standards may need to be enhanced where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality and efficiency, and to facilitate interoperability between the various electronic systems involved in the e-prescribing process. Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT standard.

Issue: **Regulatory Impact (70 Fed Reg 6269)**

We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis.

Provider Savings, especially solo and small groups (70 Fed Reg 6270)

We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.

Applying the ROI of larger practices to smaller practices (70 Fed Reg 6270)

These examples come from large practices, but we would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual or potential savings, particularly in solo and small group practices.

Response:

Without conducting a wide-ranging survey, MGMA is not in position to provide a detailed impact analysis of these proposed regulations on different types of participants. It is critical, however, that CMS develop a comprehensive and accurate report of the full costs and savings in order to fully understand the impact that this regulation will have on the industry. In particular, MGMA encourages CMS to conduct this important analysis as soon as possible as the results will not only help to guide the policy development process but may also help to facilitate the provider community's acceptance of this technology. It appears as though only a small percentage of practices are currently utilizing e-prescribing, though a significant number are expecting to move to this technology over the next 24 months. MGMA, however, is positioned and willing to develop and analyze surveys for CMS, as well as educational documentation, analysis and financial models, and pilot and testing projects.

Issue: **Application of e-prescribing rules to Part B drugs** (70 Fed Reg 6273)

Proposed definition 42 CFR 423.159: "Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs..."

Comment:

The expansion of the Part D benefit to drugs currently covered by the Medicare system remains a complex aspect of the implementation of the Part D program and the Electronic Prescription Drug Program. Many industry groups, including MGMA, assert that this nexus will result in numerous providers who did not consider themselves to be directly affected by Part D to be swept into the program's requirements, including the e-prescribing obligations.

MGMA seeks clarification, how, if at all, providers will be required to incorporate e-prescribing technologies if ordering drugs currently paid under the Part B program or acquired through the proposed Competitive Acquisition Program (CAP). The proposed rule for the CAP (CMS-1325-P; 70 Fed Reg 10746), acknowledges that drugs dispensed by venders would require a physician's order. This order would include a request for the complete treatment of the patient (multiple doses) and includes the (a) date of order; (b) beneficiary name; (c) physician identifying information, name, practice location, group practice information (if applicable) and Medicare enrollment number; (d) drug name; (e) strength; (f) quantity ordered; (g) dose; (h) frequency/instructions; (i) anticipated date of administration; (j) beneficiary Medicare information/health insurance number; (k) Medicare information; (l) shipping address; and (m) additional patient information including date of birth, allergies, height, weight, diagnosis codes, etc. We recommend that CMS ensure that all of these requirements will be able to be performed with the proposed NCPDP SCRIPT standard. It would be very burdensome if providers are required to submit some of the information through an e-prescribing system and other required data sets through a separate system, either electronic- or paper-based.

Furthermore, the proposed CAP would assign individual Medicare prescription numbers to dispensed drugs used in claims adjudication and payment. CMS should ensure that the NCPDP SCRIPT standard has the ability capture this specific number for Medicare processing.

Lastly, it remains unclear from the proposed CAP regulation, if CAP vendors would be required to use the standards established under the Electronic Prescription Drug Program. It appears that this proposed rule intends to require prescribing physicians and pharmacies/entities of any drug payable under the Medicare program to adhere to the requirements of the Electronic Prescription Drug Program. However, this additional future obligation is not made clear in the CAP regulation, or in the "CAP Vendor Application and Bid Form" or accompanying "CAP Drug Vendor Application Guide" (OMB Approval Pending No. 0938).

MGMA appreciates your consideration of these comments. If you have any questions, please contact Robert Tennant in the MGMA Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and CEO

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APR 13 2005

State of New Jersey
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RICHARD J. CODEY
Acting Governor

JAMES M. DAVY
Commissioner

ANN CLEMENCY KOHLER
Director

April 4, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program – E-Prescribing and the Prescription Drug Program
42 CFR Part 423

Dear Sirs:

This letter is in response to your request for comments on the above-referenced proposed regulation regarding E-Prescribing and the Prescription Drug Program which appeared in the Federal Register on February 4, 2005. I am writing to inform you that staff of the New Jersey Division of Medical Assistance and Health Services have reviewed the above-referenced proposed regulations and support the regulation as proposed.

We appreciate the opportunity to comment.

Sincerely,

s: Ann C. Kohler

Ann C. Kohler
Director

ACK:bpw

Sent electronically by BPU

American Academy of Dermatology Association

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APR 13

April 5, 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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FAXED
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LB 9:40Am

RE: Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

Dear Dr. McClellan:

On behalf of the 14,000 members of the American Academy of Dermatology Association, I appreciate this opportunity to comment on the proposed rule for electronic prescribing (e-prescribing) standards. These standards represent another important step on the road to developing, promoting, and integrating a national health information technology network for healthcare professionals to provide safe, quality-based, efficient and affordable patient care.

As office-based physicians, dermatologists recognize e-prescribing is as much a patient safety issue as it is a workflow issue. Indeed, the most apparent benefits for dermatologists using e-prescribing include: speedy point-to-point ordering, transmission and tracking from physician prescribers to dispensing pharmacies; reduced medication errors or duplication; increased accuracy and transparency of the transaction; improved legibility; efficiency gains in practice workflow and reduced administrative steps; as well as enhanced ability to share and coordinate patient care information.

To achieve and maintain these benefits, however, we feel strongly that the proposed federal e-prescribing standards should allow for the operational flexibility and scalability for the prescribing physicians. This would facilitate appropriate management of prescription volume and medication options, especially in ambulatory practices. Furthermore, we urge that the initial e-prescribing standards adopted for the 2006 test pilot project be designed to include the full participation of office-based specialists, including dermatologists, in both rural and urban settings in order to identify and mitigate against any potential health information technology divide and socio-economic disparity that may compromise the quality, safety, and efficiency in the delivery of patient care. Effectively, the results from proposed e-prescribing pilot testing should help address the need for physicians in small and medium-sized ambulatory practices to adopt uniform, user-friendly, and interoperable standards for the provision of safe, quality-based care.

Notwithstanding the promise of e-prescribing, the proposed federal standards should take into account, and promote elimination of prevailing barriers to adoption and usage most common among small and medium-size dermatology practices. These barriers are:

- Cost of purchasing and implementing such a system;
- Lack of interoperable capabilities between healthcare professionals to ensure effective coordination of care;
- Complex and user-unfriendly health information technology that offsets any benefits related to administering quality of care.
- Lack of reliable systems' interface with existing practice systems; and
- Lack of financial incentives for the small business provider;

These significant disincentives need to be addressed and these current obstacles removed in order to promote adoption and implementation by the key, but voluntary participant, the physician.

While the Academy is confident that e-prescribing can help advance safe, quality-based, efficient and affordable patient care, further consideration must be given to overcoming the above structural, operational and fiscal barriers. Healthcare electronic processes can be beneficial for both patients and physicians and e-prescribing is another step in the right direction.

Thank you for reviewing these comments. If you have any questions regarding our recommendations, please contact Jayna Bonfini at jbonfini@aad.org at 202-712-2614, or William Brady at wbrady@aad.org or 847-240-1824.

Sincerely,

Brett Coldiron, MD, FACP
Chair/AAD Health Care Finance Committee

FAXED
202-842-4339
9:40AM

Cc: Clay J. Cockerell, MD, President, AADA
Stephen P. Stone, MD, President-Elect, AADA
David M. Pariser, MD, Secretary-Treasurer, AADA
Ronald A. Henrichs, CAE, Executive Director and CEO, AADA
John D. Barnes, Deputy Executive Director, AADA
Judith Magel, Director, Health Policy and Practice, AADA
Laura Saul Edwards, Director, Federal Affairs, AADA
Cyndi Del Boccio, Director, Executive Office, AADA
Norma Border, Senior Manager, Coding and Reimbursement, AADA
Jayna Bonfini, Manager, Political Affairs, AADA
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National Association of Boards of Pharmacy

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April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-0011-P - "Background"

Dear Dr McClellan:

Thank you for the opportunity to submit the following information in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the Medicare Part D Electronic Prescribing Proposed Rule. Our response is relevant to the federal preemption of state law provision in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and its impact on state laws regulating the practice of pharmacy.

The National Association of Boards of Pharmacy (NABP) was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. The purpose of NABP is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. I am submitting these comments as executive director of NABP.

NABP recognizes that there is a limited need to provide for preemption and foster the development of national standards that facilitate implementation and allow for uninhibited practice across state line. However, the pre-emption should not eviscerate safeguards the states have in place protecting the patient and ensuring the safe practice of pharmacy.

NABP recommends the following principles be incorporated into the national standard addressing the electronic transmission of prescriptions. These principles are designed to assure that electronic transmission standards safeguard patient health, safety, and welfare.

A. Ensure Against Unauthorized Access
Once a prescriber has transmitted an electronic prescription, no intervening entity may alter the prescription information. Any altering by an intermediary of a prescribed drug, strength, quantity, allowed refills, or directions would adversely affect patient safety and is in direct conflict with state laws that were established to ensure the integrity of the prescribing process.

B. Authenticity and Security of Prescription
In order to assure the validity of electronic prescriptions via electronic transmission, the electronic prescriptions should be signed by use of either an electronic or digital signature. Although the Drug Enforcement Agency (DEA) standard for the electronic transmission of controlled substances (not yet released) will most likely require the use of digital signatures, many states allow an electronic signature to be used for the electronic transmission of non-controlled substances. A few states require the use of digital signatures for non-controlled substances.

C. Privacy of Individually Identifiable Health Information
The privacy and security of patient is governed by the Health Insurance Portability and Accountability Act (HIPPA). The electronic prescribing national standard should require all entities that have access to sensitive patient information to comply with the HIPPA regulations.

D. Prescriber – Pharmacist Collaboration
Collaboration between prescribers and pharmacists is a critical component of quality patient care and a growing practice. The adoption of electronic prescribing should not jeopardize this collaboration but rather strengthen the opportunity for the communication and collaboration between the prescriber and the pharmacist.

E. Patient Choice
NABP concurs with the MMA law that permits patients to obtain prescriptions from the pharmacy of their choice regardless of the technological capabilities of the pharmacy.

NABP believes that the principles highlighted provide an example of key areas that should be integral components of the MMA electronic prescribing national standard.

State Preemption
The MMA addresses preemption of state laws at section 1860D-4(e) (5) of the Act as follows:

(5) Relation to State Laws. The standards promulgated under this subsection shall supercede and State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

NABP's interpretation of this provision of the Act is that preemption of state law would only occur when there is a conflict with the Federal electronic prescription drug program requirements that are adopted under Part D. Therefore, Federal preemption would occur only if the State law or regulation directly conflicted with the Federal standards or restricted the ability to carry out this part **and** pertained to the electronic transmission of prescriptions, medication history, eligibility and/or benefits of Part D drugs for individuals enrolled in the Part D program.

"In order for a state law or regulation to be preempted under this provision, the state law or regulation would have to meet the requirements of both paragraphs (A) and (B)." In addition, before this could occur, a Federal standard, which is in direct conflict with the State law, would have to be created through a separate rulemaking.

Federal Preemption Provision Limited to Part D Drugs for Part D Enrolled Individuals
CMS specifically requested comments on "whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities."

NABP understands that many industry representatives believe that Congress intended this preemption provision to be more expansive and interpret the statute to preempt the entire field of electronic prescribing. However, NABP's interpretation of the preemption language in the Act, is that federal preemption of state law would be limited to the electronic transmission of part D covered drugs for part D enrolled individuals. Reference to federal preemption of state law with regard to non part D drugs for individuals not enrolled in Medicare Part D is absent.

Throughout the electronic prescribing section of the Act, the various provisions consistently refer to "covered part D drugs" and "part D eligible individuals". In addition to being referenced in the preemption section of the Act, examples include:

- 1860D-4(e) (1) – "Application of standards…prescriptions and other information described in paragraph (2) (A) for **covered part D drugs prescribed for part D eligible individuals** that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2)."

- 1860D-4(e) (2)(A) – "Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists….and of the following information with respect to the prescribing and dispensing of a **covered part D drug**".

- 1860D-4(e) (2) (B) – "Application to....information that relates to the medical history concerning the individual and related to a **covered part D drug** being prescribed or dispensed..."

- 1860D-4(e) (3)(E) (i) – "Permitting patient designation of dispensing pharmacy...such standards shall permit **a part D eligible individual** to designate a particular pharmacy to dispense a prescribed drug."

- 1860D-4(e) (3)(E) (ii) (II) – " No change in benefits...shall not be construed as affecting...the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a **covered part D drug**."

As evidenced above, the federal preemption of state laws language in the Act specifically addresses electronic prescribing systems used for part D drugs for part D enrolled individuals. An attempt to expand the interpretation of the Act would be contrary to the intent of the legislation and undermine the authority of the state boards of pharmacy in critical regulatory and patient care areas.

Electronic Prescription Transactions versus Paper Transactions
CMS also requested comment on "whether this preemption provision applies only to electronic prescription transactions or to paper transactions as well."

The State Board of Pharmacy or "Board" in each state is the legally constituted governmental regulatory body charged to regulate the practice of pharmacy. The Board regulates the transmission of prescriptions in all forms and modes of transmission. The electronic transmission of prescriptions, which is the scope of law, should not extend to the communication of prescription from prescriber to pharmacist via the traditional paper system. If the scope of the law is extended to this area it will unnecessarily and dangerously contravene state law with no congressional basis to take such action.

Conclusion
In closing, NABP respectfully requests that CMS recognize the importance of the electronic transmission principles mentioned in these comments and the impact these principles have on the ability of the states through the state boards of pharmacy to safeguard the health and safety of the public. Furthermore, it is imperative that the Medicare Act's section relating to state law is well-defined to avoid confusion at the state and federal levels and unnecessary or dangerous pre-emption of state laws and regulations which provide important patient safeguards. We are certain that CMS will develop standards and regulations for electronic transmission of prescriptions that enhance patient safety and foster cooperation between federal and state efforts.

Thank you, once again, for the opportunity to address this important issue.

Sincerely,

NATIONAL ASSOCATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

CAC/eza

cc: Executive Officers – State Boards of Pharmacy
NABP Executive Committee

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APR 13 2005

April 6, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: Medicare Program; E-Prescribing and the Prescription Drug Program CMS-0011-P

Dear Administrator McClellan:

This is a confirmation paper version of the comments to the above-captioned proposed rule that APA submitted online to CMS yesterday, April 5, 2005, as an attached MS Word document. Enclosed are an original and two copies of the comments. Thank you.

James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

American Psychiatric Association

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April 6, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
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RE: Medicare Program; E-Prescribing and the Prescription Drug Program CMS-0011-P

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for standards, under 42 C.F.R. Part 423, published in the Federal Register on February 4, 2005, with the title, "Medicare Program; E-Prescribing and the Prescription Drug Program."[1]

Provided there is rigorous protection of patient privacy, APA generally supports CMS' goals of enhancing patient outcomes, prescription-error reduction, and appropriate access to healthcare data. However, APA members are highly concerned about several aspects of this proposed rule on e-prescribing standards. CMS intends to accelerate physicians' adoption of e-prescribing, through proposing three standards as final foundation standards, rather than as initial standards to be pilot tested. CMS is also proposing a compliance effective date of January 1, 2006, specifically to coincide with the transition of dually eligible Medicare/Medicaid patients into Medicare Part D. APA views these as premature actions that will result in barriers to and disincentives for physicians to adopt e-prescribing.[2]

APA will detail these concerns in the ensuing comments, primarily emphasizing: 1) the impact, cost and burden on physicians electing to e-prescribe under this proposed rule; 2) negative consequences that will ensue if CMS adopts

[1] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23].

[2] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6267.

final foundation standards without pilot testing these or any other standards in 2006; 3) the adverse impact if the Secretary adopts January 1, 2006, as the effective date for compliance with e-prescribing standards; and 4) the potential for breaches in patient privacy through the technology. APA anticipates that several serious problems would arise from CMS' proposed approach to e-prescribing:

1. The three proposed final standards do not meet all the statutory criteria under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and have not yet been tested for full functionality in e-prescribing;

2. The National Committee on Vital and Health Statistics (NCVHS) recommended to CMS that it do pilot tests in 2006 for several standards functions and interoperability factors;

3. NCVHS recommended that CMS conduct pilot tests in 2006 to evaluate economic and quality-of-care impacts of automating prior authorization communications.

4. Since March 2005, after publication of the proposed rule, NCVHS made further recommendations on e-prescribing standards and privacy issues, and has an agenda to continue doing so through at least July of 2005;[3]

5. January 1, 2006, is the same effective date for the transition of dually eligible Medicare/Medicaid patients into Medicare, creating a heavy burden on physicians;

6. CMS is not confident that a National Provider Identifier (NPI) can be issued to all HIPAA "covered" dispensers and prescribers in time for a January 1, 2006, deadline;

7. January 1, 2006, does not synchronize with the initial availability in 2007 of federal matching grants for e-prescribing systems; and

8. There is only a narrow window of time to finalize and implement the statutorily mandated new Safe Harbor and new Stark II exception by January 1, 2006, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems. This is a critical shortcoming.

The degree of uncertainty with the current functional and compliance status of e-prescribing systems using the proposed standards (or others) creates a disincentive for physicians to purchase equipment and services for e-prescribing. This precisely contravenes CMS' stated goal of advancing e-prescribing within the physician community. Those who cannot easily afford e-prescribing systems, such as solo and small group practitioners, will especially be reluctant to obtain them until the support

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[3] National Committee on Vital And Health Statistics: "Final Agenda," March 3- 4, 2005. Retrieved March 30, 2005: http://ncvhs.hhs.gov/050303ag.htm

grants are available, starting January 1, 2007, and until the new Safe Harbor is clearly implemented.

Physicians will want to have solid answers about elements such as these: 1) certainty about which standards will be final; 2) whether the standards and embedding technologies will be fully integrated to allow all necessary e-prescribing functions; 3) whether the e-prescribing standards and systems will totally comply with pertinent laws; and 4) which technologies and systems will work well for various practice settings.

Until there is an established comfort level with these issues, physicians will be reluctant to commit to an e-prescribing system. Apart from a substantial initial financial outlay, they do not want to be vulnerable to costs and time-expenditures that subsequent technological changes and/or obsolescence may bring, as has been common experience with computer-based systems. They also do not want to be subject to federal sanctions for unwitting violations that non-compliant systems may engender. Also, vendors may create incentives to initiate e-prescribing through various marketing offers and other incentives that may subject physicians to violations of anti-kickback and/or Stark II laws, placing them into an untenable situation.

APA urges CMS to take these essential considerations into account, particularly as they affect psychiatrists and their patients, prior to adopting final positions on these standards-related issues.

I. "IMPACT ANALYSIS:" Impact, Cost and Burden on Physicians to E-prescribe

A. Scope and Method of E-prescribing

CMS assures physicians that e-prescribing is voluntary.[4] However, the proposed rule relegates the opt-out choice to the use of only paper-based transmissions of the information covered by the regulation, apart from phone calls. "Prescribers" must comply with specific e-prescribing technology standards, when they transmit, via electronic media, *any* of the types of information covered in the regulation, per 42 C.F.R. Sec. 423.160(a)(2).[5] These laws apply to every individual prescription-related data transmission.

The regulatory language encompasses a broad spectrum of patient information related to the prescription, in addition to the prescription itself. The "standards" for electronically transmitting this information are not found in ordinary off-the-shelf

[4] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[5] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273: "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network." 42 C.F.R. Sec. 423.159(a).

computer software. Instead, much of the available software is proprietary and uses structured data-transmission platforms, which require certain hardware, software and web-based services. Therefore, "e-prescribing" may require a costly, integrated infrastructure.

This system typically consists of a handheld wireless device like a Blackberry for portability, a linked high-performance computer system, high-speed web access, and a web-based portal that is a hub for communications among the physician and other entities. The system will require periodic software and/or data upgrades, technicians' services to customize software and assist customers, along with service contracts. Both the physician and support staff must be trained in the system's use and become proficient with it. That requires a significant time expenditure. This is a far different, more cost-intensive enterprise, than some may envision e-prescribing to be, i.e., simply writing prescriptions and sending them with any available electronic means, such as via computerized faxes with typical off-the-shelf business software.[6]

E-prescribing information transmissions render the prescriber and dispenser "covered entities" under HIPPA, therefore such transmissions must comply with HIPAA. This is why an e-prescribing regulation defers to HIPAA's comprehensive definition of what constitutes acceptable electronic media for e-prescribing. 42 C.F.R. Sec. 423.159 states that "(e)lectronic media shall have the same meaning as this term is defined in 45 CFR 160.103."[7]

> "Electronic media means:
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> (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
>
> (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission." 45 C.F.R. Sec.106.103, at 700-701.

According to this definition, faxes that start out as paper are exempt because they are not in electronic form but faxes that originate electronically as computer files must comply with the regulation. So, if a paper prescription were scanned into a computer file, then faxed from the computer, presumably, it would not be exempt, yet the same paper prescription faxed by a fax machine would be exempt. Despite the seemingly contradictory result, this is what is legally required. Computer-generated faxes are increasingly used, so the paper-fax exception provides only a minor option. Recorded

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[7] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

voice messages, if relayed elsewhere, are also covered by this law. If electronically transmitted, any and all of this information must be transmitted in compliance with these federal laws, including HIPAA, as well as state laws and managed-care contracts. This presents physicians with yet more practical and legal burdens. HIPAA compliance is automatically mandated for physicians making electronic transmissions of such information because doing so renders them a "covered entity," under HIPAA law.[8]

Apart from prescriptions themselves, the rule covers electronic transmissions of "prescription-related information." That, too, is broadly defined:

> "Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."[9]

It is difficult to envision precisely what type of patient information could *not* be construed as falling into the category of "prescription-related." The real choice for a physician is more complex than appears at first blush: 1) whether to adopt an e-prescribing system that complies with standards *whenever* an electronic transmission is used for any type of potentially covered patient information; or 2) use strictly non-electronic methods, except for paper-originated faxes and phone calls. Electronic transmission of many types of patient information from a physician is covered by this law, whether to a dispenser, pharmacy benefit manager or health plan, and whether done "directly or indirectly." While a psychiatrist or any other physician can still choose to use only telephone conversations, mailed paper and paper-originated (not computer-generated) faxes, other electronic transmissions for Medicare Part D patients must comply with the e-prescribing law. CMS has been advised to make a major compliance exception with regard for transmissions within an organization, such as a hospital or clinic.[10]

B. Burden of Cost

Control of products and services in relatively few hands diminishes competition, which drives up costs for physicians. Three major for-profit companies previously teamed up on HIPAA products using these standards and are now involved in e-

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[8] HIPAA Sec. 160.103 Definitions: "*Covered entity* means: A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."[8]

[9] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[10] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265. "The e-prescribing standards that these 'closed' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards."

prescribing. Compuware Corporation, Microsoft and Washington Publishing Company produce integrated products and services for electronic data-interchange platforms using the ASC X12N standard for claims management and HIPAA compliance. Washington Publishing Company produces a variety of technological products for physicians and other healthcare industry end-users that integrate with Microsoft products and support NCPDP and ASC X12N transactions.[11] HealthRamp and RxRite recently partnered to offer e-prescribing on the BlackBerry(R) Wireless Platform.[12]

One APA concern is that making these few standards final so soon may confer a large market share of e-prescribing business to a few major companies. It would appear that a wider range of standards would encourage market competition. Embedding these NCPDP and ASC X12N data-interchange standards into proprietary, copyrighted software and web-based services makes it harder for competitors to develop products without running afoul of other companies' copyrights. In addition, once physicians purchase an integrated e-prescribing system that includes handheld PDA devices, computers, software and web services, they are likely to be reluctant to pay more to switch system components in the near future. The early market share is likely to capture continuous users for the future. The effect of codifying specific standards into law mandating their use in e-prescribing transactions is to lock physicians into using existing standards-compatible products and services, despite their currently unknown operational problems.

CMS information on estimates of infrastructure costs for e-prescribing may be modest. CMS notes that health plans have estimated hardware and software costs for implementation of an e-prescribing system to be approximately $1500 per subscriber."[13] A cost assessment for an integrated, e-prescribing system using a handheld wireless device, such as a Blackberry, could be substantially higher. According to an article from AMA on amed.com, "(r)esearchers found that it can cost an individual physician $122,000 over five years to implement and maintain a system, although the cost can drop to $35,000 per doctor in a 50-physician practice (*Wall Street Journal*, 4/15). Also, physicians are often responsible for buying, installing and operating the systems, which can slow their workflow in the short term."[14] APA must emphasize that the majority of private-practice psychiatrists do not work within large practices, as in this example.

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[11] OnlyConnect® Retail Pharmacy Accelerator for Microsoft BizTalk Server 2002: An extension to Microsoft BizTalk Server 2002 to support National Council for Prescription Drug Programs (NCPDP) 5.1 & 1.1 transactions adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). http://www.wpc-edi.com/products/software/doctors

[12] Ramp Corporation Press Release: "HealthRamp and RxRite Partner to Offer Electronic Prescribing on the BlackBerry(R) Wireless Platform;" March 1, 2005. Retrieved March 31, 2005: http://biz.yahoo.com/prnews/050301/latu088_1.html

[13] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[14] AMA's amed.com: "E-prescribing Could Save Billions, But Adoption Lags;" April 15, 2004. Retrieved April 1, 2005: http://www.ihealthbeat.org

Instead they work solo or in small group practices that do not enjoy the ability to spread costs across a larger number. For that reason, the average psychiatrist in private practice is likely to find that purchasing an integrated e-prescribing system will be a substantial financial burden.

Here are examples of some e-prescribing system costs, not including an office computer system, software, or web-based services connectivity fees:

O2 BlackBerry 7230 Wireless Handheld: $574.95

Standards are available to members of NCPDP. Membership cost is $550/year.
Non-NCPDP members who do not wish to become members may purchase the standards, implementation guides, and/or data dictionaries at a cost of $325-$650. www.ncpdp.org

ePostRx™: "Translator" translates EDI SCRIPT messages via a web service: $2500 set up fee + an unspecified monthly payment + a per-transaction fee

ePostRx™: "Standard" $8500 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: "Professional" $16,000 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: Services and customizations are $175/hour.[15]

While the goal of required HIT standards may be to facilitate information exchange and to reduce the costs of such exchanges, the costs of acquiring standardized HIT may still be excessive for the solo practitioner. The significant costs alone are enough to discourage many practitioners from considering e-prescribing. When more potentially negative factors are added to the cost, physicians, especially psychiatrists in solo or small group practices, may determine that the disincentives to e-prescribe are overwhelming.

C. "BACKGROUND:" New Safe Harbor and Stark II Exception for E-prescribing Assistance

A new Safe Harbor and a new Stark II exception are to be promulgated at some unspecified time in the near future.[16] These would specifically allow physicians to accept non-monetary remuneration in the form of assistance to build infrastructures for e-prescribing. CMS stated in its proposed rule that Section 1860D-4(e)(6) of the MMA requires that promulgation of a new Safe Harbor and a new Stark II exception. CMS notes that it will propose the new Stark II exception "in the near future" and that the

[15] ePostRx™ website: http://www.rxrite.com

[16] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259

office of the Inspector General (OIG) will propose a new Safe Harbor.[17] Neither had apparently been done as of the proposed rule's filing date of January 27, 2005, after the OIG had published a solicitation for new or modified Safe Harbors in the Federal Register on December 10, 2004.[18] The closing date for submission of a proposed new or modified Safe Harbor was February 8, 2005. A recent search of the Federal Register did not reveal published proposals for either a new Safe Harbor or a new Stark II exception.[19] An article from the American Medical Association (AMA)'s web publication, amednews.com, on the topic indicated that, while essential to protect physicians against prosecution for accepting assistance with e-prescribing systems, these new laws have not yet been formally proposed.[20]

It will take some time to formally propose these new rules that must then go through the potentially lengthy process toward final implementation. Yet, the proposed compliance date for e-prescribing is January 1, 2006, just nine months from now. Also, this is the same effective date as will be used for the transition of dually eligible patients from Medicaid to Medicare. This transition will affect prescribing choices and methods already, and the e-prescribing requirements will simply add to the confusion. This gap in legal protection makes psychiatrists vulnerable to prosecution, should they accept any form of value related to e-prescribing that could be construed as prohibited remuneration. Clearly, it is not feasible for them to wait until the last minute to build an infrastructure for e-prescribing. If psychiatrists accept assistance with e-prescribing systems within the next few months, it will be without the benefit of the legal protections outlined above.

Until such rules are effective, any physician dealing with Medicare patients who accepts value-in-kind such as software, hardware, web-access, training, educational materials, discounts, rebates or other assistance related to e-prescribing infrastructures may be subject to federal sanctions. Managed care entities, software, computer hardware and web-services companies will make various offers to physicians, to make their products competitive and to otherwise induce them to adopt e-prescribing practices. Some of these offers may well be construed by the OIG to constitute prohibited remuneration under anti-kickback and/or Stark II anti-referral laws. CMS mentions that, "(w)e do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements

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[17] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[18] OIG Notice of Intent to Develop Regulations: "42 C.F.R. Part 1001, Solicitation of New Safe Harbors and Special Fraud Alerts;" [Federal Register: December 10, 2004 (Volume 69, No. 237)]

[19] Federal Register search March 30, 2005: http://frwebgate.access.gpo.gov

[20] American Medical Association (AMA)'s web publication: amednews.com, "Physician networks offer incentives to spur EMR use: The initiatives are among the efforts being adopted to make the technology more affordable to physicians;" March 14, 2005. Retrieved March 30, 2005: http://www.ama-assn.org/amednews/2005/03/14/bisb0314.htm

must not violate Federal and State laws prohibiting kickbacks and physician self-referrals)."[21]

E-prescribing requirements should not force psychiatrists into the difficult position of choosing to either pay the entire cost of an e-prescribing system or accept assistance from external entities but risk potential federal action. While a limited amount of acceptable help in the form of federal grant money will be available to physicians in future, it will only start being funded in 2007, the year after the proposed effective date for compliance of January 1, 2006. This will not help anyone attempting to initiate e-prescribing by the effective date in 2006.[22]

D. E-prescribing and Federal Grants

As previously noted, external assistance offered to physicians may put them at risk of falling within the definition of prohibited non-monetary remuneration. One alternative is for physicians to get matching federal grants to offset costs of e-prescribing infrastructures. But, those will only be available beginning in 2007, a full year after the proposed effective date of January 1, 2006, by which prescribers must be in full compliance with e-prescribing standards. $50,000,000 in grant money has been appropriated for fiscal year 2007. Unspecified sums are to be appropriated for 2008 and 2009, without mention of future years. Moreover, the physician applying for the grant has to agree to match at least 50% of the grant funds to cover costs for an e-prescribing program. Only one grant will be allowed per physician or per physician group.[23] Before grant money is available in 2007, many physicians may fully fund e-prescribing equipment and services purchases themselves, rather than accepting help from outside entities, to avoid any possibility of federal law sanctions.

E. Manipulation of Physicians' Prescribing Choices

APA is concerned about the potential for using this computerized technology to manipulate physicians' prescribing choices. Especially this potential exists, since profit motivates the for-profit entities that will control the drug formularies for Medicare Part D plans. Intentional bias can be integrated into hardware and software design features to influence physicians' drug choices, as well as by "messaging" commercials or other information from drug companies, pharmacies, etc. While this may seem no less innocuous than the current practice of giving physicians free drug samples, the contrast is that this influence is not overt, obvious or even of a nature to be recognized at all. It is extremely subtle as a means of manipulation. For that reason, it is difficult to recognize it

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[21] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6268.

[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

as an influence, much less actively resist it. The pharmacy industry is behind NCPDP's standards and SureScripts, Inc., which is heavily involved with e-prescribing software companies.

This industry involvement raises additional questions about incentive and bias.[24] Concerns about systems manipulation of physicians' prescribing choices were well-articulated by a panel of experts. They convened to make recommendations, published in 2004, for comparing electronic prescribing systems and selecting them to benefit patients.[25] They noted that, "(m)any developer and implementers of electronic prescribing are receiving support from third-party organizations that have incentives to influence the prescribing process."[26] Drop-down menus, order of drug choices, algorithms, graphics, visual markings, and other aspects of computerized information can subtly influence a psychiatrist's drug prescribing choices and habits. The expert panel stated that,

> "(s)ome electronic prescribing systems attempt to influence prescribers by altering the order in which medications are presented or by displaying special symbols (such as an asterisk) next to favored or disfavored options. The panel recognized that this potentially beneficial feature could also be used to create commercial advantages for third parties. To curb these potential conflicts of interest, the panel strongly recommended that the display of medication options should not be influenced by promotional considerations . . . Furthermore, the meaning of any symbols or special typefaces used to differentiate medication choices should be made clear . . ."[27]

Design and information-display bias could favor managed care companies, pharmaceutical companies or pharmacies. The psychiatrist's freedom and objectivity to determine the best choices for the patient's welfare should be retained, yet may be easily and subtly compromised in this way.

Computerized systems also offer the potential for pharmacies and pharmaceutical companies to stream commercial messages or less overt, yet influential, informational

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[24] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6266: "Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users."

[25] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004.

[26] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-312.

[27] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-309.

messages, in an attempt to affect a physician's prescribing choices. CMS does not adequately address issues of design and data bias or the influence of commercial intrusions into the systems within the proposed rule. As with design bias, psychiatrists should not be subjected to streamed information that may influence their prescribing choices, in addition to diverting their time and attention from patients.

Recommendations-Safe Harbor & Stark II: APA urges CMS to work with OIG to: 1) draft a new Safe Harbor to allow physicians to accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

Recommendations-Design Bias & Prescribing Influence: APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

II. "BACKGROUND:" Pilot Tests for Standards are Imperative

CMS has the legal authority to pilot-test proposed standards, before they are made final. Prior to issuance of this proposed rule, CMS made its position clear, as to its promotion of e-prescribing: "(a)t the July 21, 2004 Health Information Technology Summit, we (CMS) announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins." [28] The basis for proposing the adoption of several standards as final foundation standards is on the basis that there is "adequate industry experience" with them.[29]

We question whether "adequate industry experience" includes individual physicians in solo practice or those in small group practices. Therefore, we believe that standards should not be adopted as final without pilot testing of these cohorts and that more standards should be considered for pilot testing. Small scale pilot testing of e-prescribing systems with solo physicians and small group practices will help identify issues for improvement within the real-world experience of physicians. Attention must be paid to whether specialty-specific issues for psychiatrists, as well as other physicians, may well experience unique problems with these systems within their practices that pilot

[28] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[29] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6261.

tests to bring to light. Testing will also provide time to modify the technologies for maximum effectiveness, prior to widespread adoption.

CMS proposes to adopt three standards final foundation standards for e-prescribing without a pilot test. Two of these standards were developed by the National Council for Prescription Drug Programs (NCPDP), a not-for-profit Standards Development Organization, with over 1,300 members of the pharmacy-services industry.[30] Two standards have been specified by language in the new regulation, 42 C.F.R. Sec. 423.160. Therefore, these are mandated for e-prescribing transmissions: 1) NCPDP SCRIPT Standard, Version 5.0 for e-prescribing communications between prescribers and dispensers; and 2) ASC X12N 270/271 (ASC X12N), which must be used for eligibility communications between prescribers and Part D sponsors. That new regulation and the revisions to language in 42 C.F.R. Sec. 423.150 and 423.159 became effective on March 22, 2005, prior to the due date of April 5, 2005, for comments on this proposed rule on standards.[31] ASC X12N and the NCPDP Telecommunication Standard, for transmitting eligibility data between dispensers and Part D sponsors, are already adopted for and comply with HIPAA.

CMS is also considering using NCPDP standards for formulary and medication history based on the RxHub protocol; and NCPDP Provider Identification numbers for dispensers and NCPDP HCIdea, a copyrighted product for identifying prescribers.

CMS acknowledges that the three proposed final foundation standards do not meet all of the statutory criteria, under Medicare Prescription Drug, Improvement and Modernization Act (MMA).[32] In addition, they have not yet been tested for full functionality and compliance with MMA and HIPAA within integrated e-prescribing systems and by physicians within a spectrum of clinical settings.

Moreover, the National Committee on Vital and Health Statistics (NCVHS) submitted its first set of recommendations on e-prescribing standards to CMS in 2004, stating that CMS should pilot test several standards for a variety of functions.[33] In that letter to CMS, of September 2, 2004, to former HHS Secretary, Tommy Thompson, NCVHS recommended pilot tests in 2006 for:

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[30] NCPDP is accredited by the American National Standards Institute (ANSI).

[31] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[32] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[33] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson.

1. "Fill status notification" and RxNorm clinical drug terminology functions of NCPDP SCRIPT. (RxNorm provides links from clinical drugs' names to their active ingredients, components and most brand names.);[34]

2. Situational data elements and proper usage of functional acknowledgements of ASC X12N 270/271;[35]

3. Structured and codified *signatura* (SIGs) for patient instructions; and[36]

4. National prescriber identifiers (NPIs) need to be chosen and issues dealing with elements of prescriber location and connection to individual prescribers should be part of pilot testing.[37]

NCVHS also recommended pilot tests to evaluate the economic and quality-of-care impacts of automating prior authorization communications. Prior authorizations will be a major utilization management tool for formularies of Medicare Part D plans, as of January 1, 2006. If the prior authorizations are not processed smoothly, patients will have difficulty getting continuous prescription coverage on their drug regimens.

Pilot-testing the proposed standards would confer several essential advantages for psychiatrists and their patients. If pilot-testing is done in 2006, results would be evaluated, then the final standards would not be published until April 1, 2008.[38] This would have the beneficial effect of moving the effective date for compliance with the standards into a more manageable time frame, instead of rushing it to January 1, 2006. After all, this date is only a few months after the proposed rule will be finalized.

For pilot tests to be conducted in 2006, initial standards must be adopted no later than September 1, 2005.[39] However, CMS proposes to adopt three standards as final without any pilots, on the basis that they meet CMS' criteria for having "adequate industry experience." They are not proposing to adopt any initial standards that would then require pilot tests. According to NCVHS, fewer than 3% of all prescriptions are written by prescribers using an integrated e-prescribing system of some type, presumably not all with the proposed final standards. A portion of those are in the VA hospital

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[34] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.6.

[35] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.8.

[36] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.10.

[37] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.12.

[38] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[39] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

system, which uses integrated medical records and prescribing systems with its own data-transmission standards and software that is in the public domain.

Of course, CMS is aware of the widespread use of other standards within the federal healthcare system. CMS emphasized in an Executive Summary of July 2004 that "(t)here have been considerable efforts by HHS, DoD, and VA to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector."[40] CMS has lauded VA's healthcare informatics systems and suggested that they could transfer into the public sector. Moreover, their software is in the public domain, so it is more accessible than proprietary copyrighted software for companies that wish to develop products with it.[41] For these reasons, it is unclear what stands in the way of CMS adopting at least one standard in use within the federal system as an initial standard and pilot-testing it.

NCVHS noted in its letter to CMS that a standard from Health Level Seven, Inc. (HL7), is commonly used for medication orders in hospitals and clinical pharmacies and advocated coordinating HL7 with NCPDP SCRIPT. Many staff model HMOs and the VA use HL7 internally for most drug orders.[42],[43] In July 2004, HL7 issued a press

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[40] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: ". . . As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector. Additionally, the Public Health Information Network (PHIN) and the National Electronic Disease Surveillance System (NEDSS), under the leadership of the Centers for Disease Control and Prevention (CDC), have made notable progress in development of shared data models, data standards, and controlled vocabularies for electronic laboratory reporting and health information exchange. With HHS support, Health Level 7 (HL7) has also created a functional model and standards for the EHR." Retrieved March 29, 2005: http://www.healthpolicyohio.org/OHHIT/NHII_2004/HealthITStrategicFrameworkExecSummary.htm

[41] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: "The VA's report, 'Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities' (Attachment 2), also highlights its successful strategy to develop high-quality EHR technologies that remain in the public domain. These technologies may be suitable for transfer to rural and medically underserved settings. VA's primary health information systems and EHR (VistA and the Computerized Patient Record System [the current system] and HealtheVet-VistA, the next generation in development) provide leading government/public-owned health information technologies that support the provision, measurement, and improvement of quality, affordable care across 1300 VA inpatient and ambulatory settings. . . The VA is also incorporating the CHI approved standards into its next-generation HealtheVet-VistA. . . Finally, the VA's health information technologies, such as bar code medication administration, VistA Imaging, and telehealth applications, provide the VA with exceptional tools that improve patient safety and enable the increasingly geographically dispersed provision of care to patients in all settings."

[42] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265: "Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically

release announcing that the Board of Directors "had unanimously approved the Electronic Health Record System Functional Model (EHR-S) to move forward as a Draft Standard for Trial Use (DSTU). The EHR Draft Standard can now be registered with ANSI, beginning the draft standard's trial period of up to 24 months. . . An EHR standard is seen as one of the keys to supporting the exchange of information for clinical decisions and treatments, and can help lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic records."[44]

Given their widespread use, it would appear that at least some of these aforementioned standards would meet the test for "adequate industry experience" and, at least, be under consideration for status as initial standards for pilot testing. However, none of these standards appear to be under consideration by CMS at this time for adopted as initial standards and this must be done by September 1, 2005, to be pilot tested in 2006.

Presumably, any change to existing standards would require legislation to revise or add language to 42 C.F.R. Sec. 423.160. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) pre-empts state laws and prohibits them from enacting legislation that contravenes federal provisions as to e-prescribing standards.[45] So, once federal law mandates specific standards, state law cannot alter or affect physicians' compliance requirements.

APA's view is that it is unwise to forego a pilot test of the standards and technologies using them that is likely to bring to light glitches more easily worked out on a small scale than on a wide scale. It is particularly clear that integrated e-prescribing systems that communicate among prescribers, dispensers and health care plans have not been in widespread use across a variety of clinical settings. For that reason alone, it is unclear precisely what practical issues need to be resolved. Further, the extensive MMA requirements demands solid, seamless integration of multiple messaging, data translation, data transfer and data access functions using at least three standards, as well as file transfer protocols such as RxHub. The integration of these standards and technologies using them has yet to be accomplished and fully tested in the field, to ensure compliance with MMA and HIPAA. Moreover, there is the issue of how software incorporating

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use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy."

[43] Consolidated Health Informatics: "Standards Adoption Report: Messaging Standards: Retail Pharmacy Transactions;" p. 5. Retrieved March 22, 2005: http://www.whitehouse.gov/omb/egov/documents/domain3.doc

[44] Health Level Seven, Inc. (HL7) Press Release: "Board of Directors Unanimously Approves EHR for Draft Standard Status;" July 27, 2004.

[45] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

these standards will interface with web-based applications and a variety of hardware combinations.

Unless and until sufficient pilot tests are done with physicians under real-life clinical conditions to identify and resolve e-prescribing problems, CMS' laudable goals will be impeded. More importantly, once physicians begin to experience difficulties using e-prescribing systems because functionality has not yet been perfected, their frustration may well reduce or cease the use of e-prescribing altogether. In addition, negative publicity about roadblocks in the systems will deter many others from adopting e-prescribing.

Apart from time they need to properly evaluate systems against their needs, physicians also require time to become familiar with the systems, alter practices to accommodate new processes and train staff. Feedback from pilot testing will assist companies in developing physician and patient-centered products, services, training and educational materials. This will ultimately make e-prescribing more attractive and effective across various dimensions, including the enhancement of patient outcomes.

The transition to using new technologies and equipment will take physicians' time and energy. This may be more of a demand for those who do not currently own a computer. To rush this process is to increase the risk of medication errors and suboptimal patient outcomes. Those results would contravene one of CMS' primary goals for advancing e-prescribing, which is to reduce negative patient outcomes due to errors in traditional prescribing systems.

Another positive result of pilot-testing is that it would move the compliance date away from January 1, 2006. That would give psychiatrists time to plan for the substantial financial outlay for an e-prescribing system. The expanded time window will also allow psychiatrists to apply for federal matching grants for e-prescribing systems. These grants will not be funded until 2007. In addition, legislators will get more time to implement the projected new Safe Harbor and the new Stark II exemption that are intended to allow physicians to accept non-monetary assistance for e-prescribing systems without violating current federal laws.

Recommendations: APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards with physicians, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

III. "PROVISIONS:" The Secretary's Proposed Effective Date of January 1, 2006, for E-Prescribing Compliance is Premature and Carries Adverse Implications

A. Prematurity of the Proposed Effective Date

The HHS Secretary has the discretion to choose a more practical and appropriate effective date for e-prescribing compliance than January 1, 2006, and APA urges him to do so. This date is premature for several reasons and adopting it will produce adverse effects for physicians and their patients. It will also discourage psychiatrists and other physicians from adopting e-prescribing, until many technological and practical issues area resolved. The following are some of the reasons why January 1, 2006, is not a judicious choice as an effective date for compliance with e-prescribing:

1. January 1, 2006, is the same effective date for transition of dually eligible Medicare/Medicaid patients into Medicare, which will already be burdensome for physicians and patients;

2. CMS admits that it may not be possible to issue a National Provider Identifier (NPI), as planned, for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline. In addition this date is earlier than the current HIPAA compliance date for using an NPI for covered e-prescribing transactions;

3. January 1, 2006, is premature and does not synchronize with the availability of federal matching grants for physicians' e-prescribing systems, which begin being funded in 2007;

4. January 1, 2006, does not allow sufficient time to finalize a new Safe Harbor and a new Stark II exception, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems, without rendering them vulnerable to federal prosecution under current anti-kickback and Stark II laws; and

5. CMS notes that it may not be possible to issue a National Provider Identifier (NPI) for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline, which would be earlier than the current compliance date for HIPAA covered transactions. Thus, it would be impossible for physicians to be in compliance in using a HIPAA-required NPI, if they are not issued one before the deadline. E-prescribing transmissions will make physician-prescribers covered entities for HIPAA compliance. We believe that psychiatrists should not be legally mandated to use an NPI until it exists and that confusion about which identifier will be required should be resolved prior to any compliance effective date. Alternative identifiers for e-prescribing could be the physician's medical license number, DEA number, EIN or Social Security number.

Recommendation: APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

B. "IMPACT ANALYSIS:" Privacy Concerns

Patient privacy is particularly critical in ensuring high quality psychiatric care. Psychiatrists are also rightly concerned about how e-prescribing technologies, such as web-based portals, may compromise their patients' privacy, and hence impair the foundation of trust that is the core of the psychiatrist-patient relationship. It is not until pilot tests sort out these and other potential issues that psychiatrists are likely to gain sufficient comfort with adopting e-prescribing techniques. We remain concerned about the inadequate safeguards to potential breaches in the security of identifiable patient information, through electronic transmissions and databases. It is critically important to ensure the security of and to prevent hacking into electronic systems, especially as regards the confidentiality of patients' medications. As a consequence, CMS must address this e-prescribing issue directly.

Regrettably, confidentiality is too often overlooked as an essential element of high-quality health care. Out of fear of disclosure, some patients simply will not provide the full information necessary for successful treatment. Others refrain from seeking medical care or drop out of treatment, in order to avoid any risk that their records are not entirely private. With regard to e-prescribing and its use of the internet and other electronically accessible databases, this fear may be heightened for some psychiatric patients, especially those with paranoid features to their illness. A psychiatrist is hard-pressed to assure a patient about confidentiality when there are headlines about databank breaches.

A pharmacist can legally contact a list of his or her pharmacy's patients, who have been prescribed certain drugs, in order to inform them about alternative drug therapies. A pharmaceutical company can pay the pharmacist to do this, though it cannot directly obtain patient information and contact patients. This allows pharmaceutical companies to indirectly promote targeted drugs to patients. Also, pharmacies can promote their own financial interests by urging a patient to use medications that are more profitable for the pharmacy. Marketing communications do not necessarily need to disclose these compensation arrangements.

APA believes that patients need to be certain that there will be no downstream release of information to marketers and that the security of their health records will be safeguarded. A strong CMS policy to that effect would give vendors a clear message of CMS' expectations, as this applies to e-prescribing systems and security. It is critically important that CMS respond to the e-prescribing security concerns of psychiatrists, as well as all physicians, and their patients.

As mentioned above, mental health records are particularly sensitive to release and disclosure, partly due to the unfortunate, pervasive social stigma about mental disorders. A patient might not want family, neighbors, or even a postal delivery person to see a postcard from a pharmacy suggesting that he or she is on psychotropic medication.

Such communications could undermine mental health care, as patients avoid or delay it, to avoid stigmatization.

CONCLUSION AND RECOMMENDATIONS

APA maintains that the goals and mission of effectuating widespread adoption of e-prescribing within the physician community will be fraught with barriers, unless CMS adopts a more judicious, cautious approach. Pilot testing of standards within their actual context of usage is imperative, along with a more realistic, workable effective date for e-prescribing compliance. What may constitute "adequate industry experience" with standards within one context, i.e., intra-entity transmissions or within partial e-prescribing systems, may well not work as anticipated within a different environment. For instance, problems may arise when psychiatrists, or, indeed, any physicians, in a small group practice use a fully integrated e-prescribing system to communicate with managed care companies and external pharmacies using different systems.

Only after evaluating the results of e-prescribing pilot projects using different systems across a spectrum of clinical settings, will it be feasible to determine precisely which standards, process areas or technologies require adjustment. All standards to be used for e-prescribing must have the capability of being used within products that work seamlessly across different data-interchange platforms and among all entities involved in the prescribing process. Moreover, the standards ultimately adopted as final foundation standards to be embedded within software, used via web portals and within e-prescribing systems hardware must be efficiently inter-functional and meet the intended practical and legal requirements. It will take some time to discover how to perfect these systems and CMS must not foreshorten this process, or it will prove to ultimately be at the expense of patients.

Psychiatric patients on prescription psychotropics are especially vulnerable to delays, glitches, and errors that could be caused by premature adoption of standards, resulting in ineffective systems. Since medication adherence is already a serious issue for such patients, even delays of a day or two in receiving prescription fills could seriously and adversely affect them. It will be much easier to collect data, provide feedback loops, and create corrective interventions within a smaller pilot-test system of e-prescribing, than within a large one. Moreover, fewer physicians and patients will be negatively affected when something goes awry within a pilot test, than within a wider context of usage. It simply makes practical sense to evaluate a major change of this dimension on the prescribing mechanisms for physicians on a small scale, before expanding the process into a larger patient-care environment.

Successes within the pilot tests can then be used to encourage further adoption of e-prescribing, while physicians remain confident that obstacles to effective use will be resolved at the pilot stage, before they adopt the technologies. In this way, e-prescribing will become a more palatable alternative to physicians, who will have a more definitive set of reasons to adopt it, with solid evidence of its advantages and confidence in its practicality. Physicians also require reassurance from CMS that policies will be adopted

that send a clear message to companies that commercial messages and design bias in software and hardware for e-prescribing will not be tolerated.

Pilot testing in 2006 will automatically advance the effective date for compliance, which has the added benefit of allowing sufficient time to promulgate the new Safe Harbor and new Stark II exception that give physicians the freedom to accept assistance in establishing e-prescribing systems. It will also be in line with the timeframe that will ensure physicians' access to federal grants to underwrite such systems. APA's specific recommendations are reiterated, below:

Recommendations-Safe Harbor & Stark II: APA urges CMS to work with OIG to: 1) draft a new Safe Harbor for physicians to freely accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

Recommendations-Design Bias & Prescribing Influence: APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

Recommendations-Pilot Testing: APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

Recommendation-Effective Date: APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

Thank you for your consideration of these comments.

James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

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APR 13

AHIP

April 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Notice of Proposed Rulemaking for Electronic Prescribing and the Medicare Drug Program

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Notice of Proposed Rulemaking (the "NPRM") for Electronic Prescribing and the Medicare Prescription Drug Program published in the *Federal Register* on February 4, 2005 (70 Fed. Reg. 6256).

AHIP is the national trade association representing the private sector in health care. Our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans, including over 4.2 million Medicare Advantage enrollees.

Development of these standards, as authorized by the Medicare Modernization Act of 2003 (MMA), is an important step toward enabling electronic prescribing for the Medicare Part D program and within the health care community as a whole. AHIP supports the electronic prescribing initiative and we appreciate the opportunity to provide our recommendations to help facilitate the development of appropriate standards for electronic prescribing.

Application of Standards Within Organizations

Issue: The standards should not be applied to electronic prescribing communications within a "closed network."

Discussion: The NPRM defines "e-prescribing" as the electronic transmission of information "between a prescriber, dispenser, pharmacy benefit manager, or health plan...." (45 CFR 423.159) The NPRM applies the standards to transactions between different entities, such as an electronic eligibility transaction between a Medicare Advantage Prescription Drug Plan and a prescribing physician. The Preamble to the NPRM requests public comment about whether the standards should also apply within a specific organization (a "closed network").

Our interpretation is that the e-prescribing definition does not include situations where various parts of an entity access health information through one or more databases within a single enterprise. Such internal communications within an organization or "closed enterprise" are not within the scope of the MMA standards because such processes are not a transmission of data requiring compliance with electronic prescribing standards. The National Committee on Vital and Health Statistics agreed with this approach by recommending that the standards not be applied to closed networks and that they only govern transactions sent outside of such organizations.

The standards are intended to establish common communication protocols for electronic transactions involving separate and distinct entities. Many entities have made significant investments in technology and processes to support transactions within their enterprise. Establishing standards for transactions within a single entity is not necessary because each entity can easily determine the most appropriate security and communication protocols to meet its unique business and operational needs.

Recommendation: AHIP recommends that the standards not apply to closed networks. We suggest that CMS adopt a definition of "closed enterprise" for purposes of identifying communications within an enterprise that would be outside the scope of these rules. We propose that CMS define a closed enterprise by reference the Health Insurance Portability and Accountability Act (HIPAA) definition of "organized health care arrangement" (45 CFR 160.103).

Pilot Testing

Issue: Pilot testing of the proposed electronic prescribing standards is critical and should be required prior to final implementation even if the standards are currently being used by some health care providers, pharmacy benefit managers or health insurance plans.

Discussion: The MMA provides that the electronic prescribing standards must be pilot tested unless the Secretary determines there is "adequate industry experience" with the standards. The NPRM recommends the adoption and implementation effective January 1, 2006 of three

standards for communicating eligibility and prescription or prescription-related information without pilot testing.[1] AHIP does not believe there is adequate experience with these standards and recommends pilot testing prior to final adoption. Implementation of the three standards should be delayed or made voluntary between trading partners until pilot testing is completed.

Although the standards proposed by the NPRM may be in use by some health care providers and payers, there is not widespread utilization of the standards throughout the health care community. Pilot testing will provide valuable information about the application of the standards in a variety of settings (e.g. among different types and sizes of organizations, varying transaction volumes and system capabilities, etc.). Pilot testing will allow the standards to be reviewed against the specific requirements of the Medicare Part D program.

Recommendation: AHIP recommends that the three proposed electronic prescribing standards should be pilot tested before final adoption and implementation.

Standards for Formulary Representation and Medication History

Issue: The standards for communicating formulary information and medication history should be developed through the HIPAA approved standards development organizations (SDOs).

Discussion: The NPRM notes that standards are needed to permit communication of formulary information and medication history. Public comment is requested regarding the adoption of the RxHub protocol as a basis for these standards. The Preamble to the NPRM notes that the protocol has been submitted for review to the National Council for Prescription Drug Programs (NCPDP), a HIPAA approved standards development organization.

NCPDP is the appropriate organization to evaluate the proposed standards for communicating formulary information and medication history. Once NCPDP has finalized its review of RxHub or other protocols for communicating formulary information and medication history, the standards should be pilot tested and implemented.

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[1] The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12 2004 (for certain messaging transactions); the American Standards Committee X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002 (for eligibility inquiries and responses between prescribers and Part D sponsors); and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) (for eligibility inquiries and responses between dispensers and Part D sponsors).

Recommendation: AHIP recommends that NCPDP be allowed to complete its review to determine whether the RxHub protocol as an appropriate standard for communicating formulary information and medication history.

Process for Modifying the Standards

Issue: The Centers for Medicare and Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed process for approving modifications to the standards through an annual interim final rulemaking process. Covered entities should be permitted a period of time to continue using older versions of the standards.

Discussion: The MMA established a process for the initial development of electronic prescribing standards. The NPRM requests public comments regarding a process for modifying standards once they are initially adopted.

When evaluating a change process, we recommend CMS evaluate the "lessons learned" from the implementation of the HIPAA electronic transaction standards. HIPAA requires any modifications to those standards to undergo a lengthy review and rulemaking process before implementation. Under this process, it can take up to several years to make necessary changes to an existing standard.

It is important for electronic prescribing standards to be sufficiently flexible to meet changing business needs and advances in technology. As a result, appropriate modifications should be adopted in a timely fashion.

CMS should work with health care community stakeholders to develop an agreed process for the annual adoption of modifications to the electronic prescribing standards. The Standards Development Organization that initially developed an electronic prescribing standard, such as NCPDP, should follow its defined process for review and recommendation for modifying the standard. These modifications should be submitted directly to CMS which should release them as an interim final rule with a 60 day comment period. Once the comment period is completed, the modifications should be implemented within a reasonable time frame.

Covered entities should be given the option to continue using older versions of the standards for a period of time after the modifications are adopted and implemented to allow any necessary changes to technology and business systems.

Recommendation: AHIP encourages CMS to adopt a standards modification process that allows annual modifications to the standards. Covered entities should be permitted to continue using older versions of the standards for a period of time after those modifications are adopted.

The National Provider Identifier

Issue: Covered entities should be permitted to use proprietary or other identifiers for health care providers prior to the implementation of the National Provider Identifier (NPI) standard.

Discussion: The NPRM solicited public input about an appropriate methodology to identify health care providers. The final rule mandating a National Provider Identifier (NPI) for health care providers was published in January 2004. Although providers can begin applying for a NPI in May 2005, most covered entities are not required to begin using the national provider identifier until May 2007 ("small health plans" have until May 2008 to come into compliance with the NPI requirements).

Until the NPI compliance date is in effect, AHIP recommends that electronic prescribing standards allow the NPI as well as other identifiers to be used. Health insurance plans, health care providers, and pharmacy benefit managers are already accustomed to using a variety of identifiers including proprietary numbers, the Medicare provider number, Drug Enforcement Agency (DEA) provider numbers, the NCPDP provider identifier for pharmacies, and tax identification numbers. Some health care providers will apply for an NPI before the implementation date while other providers may need additional time to come into compliance.

Recommendation: AHIP recommends that until use of the NPI is required, CMS should allow either the NPI or other identifiers to be used for electronic prescribing.

State Law Preemption

Issue: The final rule should indicate that the standards preempt all state laws or regulations that restrict or prohibit the electronic transmission of information with respect to drugs prescribed to Medicare beneficiaries. The Department of Health and Human Services should review existing state laws and regulations and provide guidance regarding preemption.

Discussion: The MMA provides for federal preemption of state laws or regulations: (1) that are contrary to or restrict the ability to carry out the electronic prescribing provisions of the MMA; and (2) that pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions for drugs covered under Part D.

There are a variety of state laws and regulations that relate to the exchange of information by and between health care providers, health insurance plans, and pharmacy benefit managers. For example, some state laws restrict the use of electronic prescribing without express consent of a patient.[2] Other state laws require the State Board of Pharmacy to approve electronic transaction and data security standards.[3]

Health care providers, health insurance plans, and pharmacies and pharmacists will participate in electronic prescribing only if they are assured that they will not be in violation of state laws that govern their conduct. It is critical that CMS interpret the preemption language broad and consistent with the intent of the MMA so that any state law that "restricts the ability to carry out the electronic prescribing provisions of [the MMA]" will be preempted. CMS must also work to identify possible state conflicts and provide guidance regarding the impact of the electronic prescribing standards on those state laws.

Recommendation: AHIP recommends that CMS broadly interpret its federal preemption authority. CMS should evaluate and specifically identify state laws and regulations that are federally preempted for electronic prescribing and issue regulations, bulletins, or other guidance explaining its preemption authority.

We appreciate the opportunity to comment on these important proposals.

Sincerely,

Diana C. Dennett
Executive Vice President

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[2] *See e.g.:* Nev. Admin Code §639.7105 and Wis. Stat. Ann. §460.11.

[3] The National Association of State Boards of Pharmacy identified a number of state requirements that could be interpreted as conflicting with federal electronic prescribing standards in testimony to the NCVHS Subcommittee on Standards and Security last year.

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APR 25

OREGON MEDICAL ASSOCIATION
John C. Moorhead, MD, President

April 7, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Re: 42 CFR Part 423 [File Code CMS-0011-P] RIN-0938-AN49

Dear Dr. McClellan:

The Oregon Medical Association (OMA) on behalf of its 7,000 members appreciates the opportunity to again provide comment on the final regulations regarding the new Prescription Drug Benefit Program. The Association feels CMS took into consideration a number of the concerns voiced by organized medicine. This letter serves to reiterate our positions on several issues we have previously noted. Our belief is that several serious concerns still exist in the final rule.

Under the proposed rules, Prescription Drug Plans (PDPs) had to offer at least two drugs per class. This does not appear to be clarified or resolved in the final rule where the possibility exists that further drugs in each class can be restricted. We raise concerns about a classification that has the potential to place patients and physicians in the position of not having clinically appropriate medications available for particular diseases and illnesses. Since the federal legislation preempts state law and regulations, physicians could find themselves more vulnerable to litigation because a plan limiting the drug armamentarium available for patients might not comply with the current standard of practice.

As you know, Oregon was one of the first states to adopt legislation using evidence-based information to determine the most clinically appropriate and cost effective medications for the Medicaid program. This legislation, however, provides that physicians may prescribe medications that are not on the formulary based on their medical judgment and the clinical needs of the patient. The Medicaid program does cover the cost of the prescription even though a drug may not be on the preferred drug list. This is particularly troubling for physicians who treat patients with multiple medical problems. The new federal program could force chronically ill patients to change medications, not only upon initial implementation, but conceivable several times during the year since the final rules continue to allow changes in the formulary [albeit it 60 days instead of 30 as called for in the proposed regulations].

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There are no clear assurances regarding the clinical expertise of those on the P & T committee. The OMA believes that these regulations must be more proscriptive regarding the make-up and authority of these committees. In our opinion, the committee should be composed of a majority of physicians and pharmacists who are independent of the PDP - otherwise the validity of the extent or limitations of the benefit could be called into question based on concerns of whether the benefit design was based more on cost rather than clinical issues. In order to assure the public that the activities of the P & T Committees are based on appropriate clinical considerations, their deliberations should, to the extent reasonable, be open to the public, with public input allowed after appropriate notification prior to finalizing a benefit plan.

The final regulation does not allow an appeal from the pharmacy at the time of the denial or substitution but imposes a burden on beneficiaries to submit any appeals in writing. Clearly, many patients will not be in a position due to medical conditions, like dementia, frailty or serious mental illness, making this process both impractical and illogical. The final rule also does not allow for the patient to seek a reduction in the co-payment for non-formulary drugs. The OMA urges CMS to reconsider this position.

We are concerned about the transition of dual eligible patients to Prescription Drug Plans. The OMA urges CMS to determine a more deliberate transition process that fully considers the implications for patients, physicians and state programs that will be forced to deal with the huge surge of confused and bewildered patients who will seek assistance during the limited transition period. We had previously recommended that the time period for dual-eligibles to select a plan [before they are enrolled automatically] be extended. Additionally, our recommendation was for Part D plans to be required to reimburse current pharmacies for current medications for at least three months. There does not appear to be any accommodation for transitional or "wrap-around" coverage in the final rule.

OMA is aware of the importance of this program to the beneficiaries in Oregon. The OMA supports separate comments provided to CMS by the American Medical Association and urges you to consider these and all other comments prepared by the medical profession. We are hopeful that CMS will work with the medical community a in its design of an enormously complex program. In spite of our concerns we realize the potential this program has for the many Medicare and Medicaid patient nationwide. We thank you for the opportunity to be heard.

Sincerely,

John Moorhead

John C. Moorhead, M.D.
President

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

5874

no number

March 3, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via: http://www.cms.hhs.gov/regulations/ecomments

The National Committee on Vital and Health Statistics (NCVHS) was called upon by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to develop recommendations for uniform standards to enable electronic prescribing (e-prescribing) in ambulatory care. The initial recommendations were delivered September 2, 2004. The Committee is very pleased to find that these recommendations were helpful in drafting the Medicare Program E-Prescribing and the Prescription Drug Program Proposed Rule. This letter includes the NCVHS comments in response to the Proposed Rule in the response format requested.

BACKGROUND
A. Statutory Basis

NCVHS recognizes that the HHS Proposed Rule must be consistent with the wording in MMA, including the wording, "e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans." However, NCVHS also believes that HHS should ensure that e-prescribing standards are not only appropriate for Medicare Part D users but also consistent with the standards for all types of prescribers, dispensers, and public and private sector payers. This is necessary to avoid barriers to interoperability across healthcare domains. To achieve this, e-prescribing standards for Medicare Part D should also be compatible with those adopted as HIPAA and CHI standards, and with those recommended in November 2003 by NCVHS for clinical data terminologies, especially with those pertaining to RxNorm.

F. Evolution and Implementation of an Electronic Prescription Drug Program

(7)

There are lessons learned from HIPAA regarding both the value of standards and the need for flexibility to respond to industry requirements and technology changes. There are a number of approaches that could be considered to provide the industry greater flexibility and ability to advance, while maintaining standardization of messages and data. For example, CHI has set a precedent for this by adopting a version of its clinical information standards as a baseline, from which new versions may be adopted by the industry when ready; even though this process is different from the process required for standards adopted under HIPAA. HHS should work with the industry in its rulemaking process to determine how best to afford flexibility in keeping standards in pace with the needs of the industry, including standards for HIPAA and e-

prescribing transactions. For example, HHS might consider recognizing new versions of standards, without a separate regulation, if they are backward compatible.

PROVISIONS
C. Proposed Requirements for Part D Plans

The NCVHS recommendation relative to e-prescribing standards adoption within "closed" environments is different from the HIPAA transaction requirements where the Rule applies to both "closed" and "open" environments. NCVHS observes that HL7 is commonly used to communicate medication orders within a hospital, and with clinical pharmacies within an enterprise. Coordination of the HL7 data elements for order entry messages with the NCPDP SCRIPT Standard data elements for e-prescribing messages (which are used to communicate prescriptions to community and retail pharmacies) would result in functions being more seamless across healthcare environments. This would remove a major barrier to adoption of electronic medication ordering and prescribing. HL7 and NCPDP have already begun this coordination by mapping the data elements in their respective standards that support common functions. NCVHS believes that HHS should recognize the exchange of prescription transactions ***within the same enterprise***[1] as outside the scope of MMA e-prescribing standard specifications. However, HHS should require that prescription orders sent using HL7 messages within an enterprise be translated to NCPDP SCRIPT message format if the message is being transmitted to a dispenser outside of the enterprise. HHS also should require that any retail pharmacy within an enterprise be able to receive prescription transmittals via NCPDP SCRIPT from outside the enterprise.

E. Proposed Standards
1. Prescription

NCVHS observes an apparent inconsistency in the description of the proposed standards to be adopted regarding the Prescription Fill Status Notification Transaction. On page 50 of the text version of the Proposed Rule, the Prescription Fill Status Notification Transaction (and its three business cases) are correctly excluded from the foundation standards. However, on page 53 of the text version of the Proposed Rule it incorrectly states that there is industry experience with the Fill Status Notification Transaction. The sentence on page 53 that needs to be corrected is: "More specifically, the NCPDP SCRIPT Standard transactions we propose for adoption have been used extensively for messaging between prescribers and retail pharmacies for new prescriptions, prescription refill requests, prescription fill status notifications, and cancellation notifications, as part of the Consolidated Health Informatics (CHI) Initiative."

E. Proposed Standards
2. Eligibility

NCVHS supports the adoption of the ASC X12N 270/271 transactions for conducting eligibility and benefits inquiries between prescribers and Part D sponsors and the NCPDP Telecommunication Standard for conducting eligibility transactions between dispensers and Part D sponsors. NCVHS would like to emphasize the importance of the note within the proposed

[1] NCVHS recognizes that properly defining "enterprise" may be complex. NCVHS encourages the Secretary to clarify the definition in rulemaking.

rule that "the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request." In addition, the proposed rule indicated that "if standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards." NCVHS believes the process of potentially accepting as compliant different versions of the standards that are backward compatible is critical to keeping the e-prescribing process current. This should apply to all applicable standards, including, for instance, the X12 278 Prior Authorization standard and others.

NCVHS is pleased to provide these comments in support of advancing the principles and purposes of e-prescribing.

Sincerely yours,

Simon P. Cohn, MD/bs

Simon P. Cohn, M.D., M.P.H.
Chairman, National Committee on
Vital and Health Statistics

Cc: HHS Data Council Co-Chairs

ESH

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April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-0011-P - "Background"

Dear Dr McClellan:

Thank you for the opportunity to submit the following information in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the Medicare Part D Electronic Prescribing Proposed Rule. Our response is relevant to the federal preemption of state law provision in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and its impact on state laws regulating the practice of pharmacy.

The National Association of Boards of Pharmacy (NABP) was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. The purpose of NABP is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. I am submitting these comments as executive director of NABP.

NABP recognizes that there is a limited need to provide for preemption and foster the development of national standards that facilitate implementation and allow for uninhibited practice across state line. However, the pre-emption should not eviscerate safeguards the states have in place protecting the patient and ensuring the safe practice of pharmacy.

NABP recommends the following principles be incorporated into the national standard addressing the electronic transmission of prescriptions. These principles are designed to assure that electronic transmission standards safeguard patient health, safety, and welfare.

A. Ensure Against Unauthorized Access
Once a prescriber has transmitted an electronic prescription, no intervening entity may alter the prescription information. Any altering by an intermediary of a prescribed drug, strength, quantity, allowed refills, or directions would adversely affect patient safety and is in direct conflict with state laws that were established to ensure the integrity of the prescribing process.

B. Authenticity and Security of Prescription
In order to assure the validity of electronic prescriptions via electronic transmission, the electronic prescriptions should be signed by use of either an electronic or digital signature. Although the Drug Enforcement Agency (DEA) standard for the electronic transmission of controlled substances (not yet released) will most likely require the use of digital signatures, many states allow an electronic signature to be used for the electronic transmission of non-controlled substances. A few states require the use of digital signatures for non-controlled substances.

C. Privacy of Individually Identifiable Health Information
The privacy and security of patient is governed by the Health Insurance Portability and Accountability Act (HIPPA). The electronic prescribing national standard should require all entities that have access to sensitive patient information to comply with the HIPPA regulations.

D. Prescriber – Pharmacist Collaboration
Collaboration between prescribers and pharmacists is a critical component of quality patient care and a growing practice. The adoption of electronic prescribing should not jeopardize this collaboration but rather strengthen the opportunity for the communication and collaboration between the prescriber and the pharmacist.

E. Patient Choice
NABP concurs with the MMA law that permits patients to obtain prescriptions from the pharmacy of their choice regardless of the technological capabilities of the pharmacy.

NABP believes that the principles highlighted provide an example of key areas that should be integral components of the MMA electronic prescribing national standard.

State Preemption
The MMA addresses preemption of state laws at section 1860D-4(e) (5) of the Act as follows:

(5) Relation to State Laws. The standards promulgated under this subsection shall supercede and State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

NABP's interpretation of this provision of the Act is that preemption of state law would only occur when there is a conflict with the Federal electronic prescription drug program requirements that are adopted under Part D. Therefore, Federal preemption would occur only if the State law or regulation directly conflicted with the Federal standards or restricted the ability to carry out this part **and** pertained to the electronic transmission of prescriptions, medication history, eligibility and/or benefits of Part D drugs for individuals enrolled in the Part D program.

"In order for a state law or regulation to be preempted under this provision, the state law or regulation would have to meet the requirements of both paragraphs (A) and (B)." In addition, before this could occur, a Federal standard, which is in direct conflict with the State law, would have to be created through a separate rulemaking.

Federal Preemption Provision Limited to Part D Drugs for Part D Enrolled Individuals
CMS specifically requested comments on "whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities."

NABP understands that many industry representatives believe that Congress intended this preemption provision to be more expansive and interpret the statute to preempt the entire field of electronic prescribing. However, NABP's interpretation of the preemption language in the Act, is that federal preemption of state law would be limited to the electronic transmission of part D covered drugs for part D enrolled individuals. Reference to federal preemption of state law with regard to non part D drugs for individuals not enrolled in Medicare Part D is absent.

Throughout the electronic prescribing section of the Act, the various provisions consistently refer to "covered part D drugs" and "part D eligible individuals". In addition to being referenced in the preemption section of the Act, examples include:

- 1860D-4(e) (1) – "Application of standards…prescriptions and other information described in paragraph (2) (A) for **covered part D drugs prescribed for part D eligible individuals** that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2)."

- 1860D-4(e) (2)(A) – "Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists….and of the following information with respect to the prescribing and dispensing of a **covered part D drug**".

- 1860D-4(e) (2) (B) – "Application to....information that relates to the medical history concerning the individual and related to a **covered part D drug** being prescribed or dispensed..."

- 1860D-4(e) (3)(E) (i) – "Permitting patient designation of dispensing pharmacy...such standards shall permit **a part D eligible individual** to designate a particular pharmacy to dispense a prescribed drug."

- 1860D-4(e) (3)(E) (ii) (II) – " No change in benefits...shall not be construed as affecting...the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a **covered part D drug**."

As evidenced above, the federal preemption of state laws language in the Act specifically addresses electronic prescribing systems used for part D drugs for part D enrolled individuals. An attempt to expand the interpretation of the Act would be contrary to the intent of the legislation and undermine the authority of the state boards of pharmacy in critical regulatory and patient care areas.

Electronic Prescription Transactions versus Paper Transactions
CMS also requested comment on "whether this preemption provision applies only to electronic prescription transactions or to paper transactions as well."

The State Board of Pharmacy or "Board" in each state is the legally constituted governmental regulatory body charged to regulate the practice of pharmacy. The Board regulates the transmission of prescriptions in all forms and modes of transmission. The electronic transmission of prescriptions, which is the scope of law, should not extend to the communication of prescription from prescriber to pharmacist via the traditional paper system. If the scope of the law is extended to this area it will unnecessarily and dangerously contravene state law with no congressional basis to take such action.

Conclusion
In closing, NABP respectfully requests that CMS recognize the importance of the electronic transmission principles mentioned in these comments and the impact these principles have on the ability of the states through the state boards of pharmacy to safeguard the health and safety of the public. Furthermore, it is imperative that the Medicare Act's section relating to state law is well-defined to avoid confusion at the state and federal levels and unnecessary or dangerous pre-emption of state laws and regulations which provide important patient safeguards. We are certain that CMS will develop standards and regulations for electronic transmission of prescriptions that enhance patient safety and foster cooperation between federal and state efforts.

Thank you, once again, for the opportunity to address this important issue.

Sincerely,

NATIONAL ASSOCATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

CAC/eza

cc: Executive Officers – State Boards of Pharmacy
NABP Executive Committee

28

United States Senate

JUL 28 2005

July 26, 2004

CMS-0011-P

Simon P. Cohn, M.D.
Chair
Subcommittee on Standards and Security
National Committee on Vital and Health Statistics
c/o Maria Friedman, D.B.A.
Centers for Medicare & Medicaid Services
Mail Stop S2-26-17
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Implementation of the Medicare Modernization Act (MMA) Electronic Prescribing Program

Dear Dr. Cohn:

Ensuring that Medicare beneficiaries receive a high-quality, affordable prescription drug benefit was a fundamental goal of last year's Medicare Modernization Act (MMA, P.L. 108-173). The MMA includes several provisions to achieve that objective, including those to promote the broad adoption of electronic prescribing practices.

In crafting the electronic prescribing provisions, Congress sought to address a number of issues that could undermine the potential of improved quality, patient safety, and efficiency that electronic prescribing holds. It is my understanding that the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security is holding hearings to inform its recommendations for the initial uniform standards for the electronic prescribing program. As the Subcommittee continues its work, I want to call your attention to specific MMA provisions aimed at addressing issues that could compromise electronic prescribing programs and the underlying intent of these provisions.

1. **Permitting Use of Appropriate Messaging [42 U.S.C. §1395w—104(e)(3)(D)]:** The MMA requires that electronic prescribing standards, "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse drug interactions, and to improve medication use."

   The provision is intended to preclude the transmission of commercial information and to ensure the presentation of neutral and unbiased information with the ultimate objective of protecting patient choice. The Conference Report clarifies Congress' intent by stating the following:

(a) The conferees do not intend for electronic prescribing, "to be used as a marketing platform or other mechanism that could unduly influence physicians' clinical decisions." H.R. Conf. Rep. No 108-391, at 456 (2003).

(b) The conferees intend, "for prescribing health professions to have ready access to neutral and unbiased information on the full range of covered outpatient drugs available." H.R. Conf. Rep. No 108-391, at 455 (2003).

2. **Real-time delivery of patient information [42 U.S.C. §1395w-104(e)(2)(D)]:** The MMA states that "to the extent feasible information exchanged under this paragraph through electronic prescribing shall be on an interactive, real-time basis." While Congress understands that real-time interaction is an important aspect of highly-developed electronic prescribing programs, we also recognize that some providers will have to take significant steps to acquire that capacity. Since our goal is to promote adoption of electronic prescribing practices, the Conference Report clarifies that it is Congress' intent not to "preclude an entity from participating in an electronic prescribing program by virtue of such entity's inability to transmit information on an interactive, real-time basis." H.R. Conf. Rep. No 108-391, at 455 (2003).

I understand that the NCVHS Subcommittee has a substantial amount of work to complete. I request that you inform me in writing about your efforts to develop interim standards consistent with these provisions. Should my staff have additional questions, I would appreciate your taking the time to meet with them to discuss your response in greater detail. The success of electronic prescribing programs depends on the effective resolution of these issues, and I commend the NCVHS Subcommittee for its commitment to exploring them fully prior to submitting its recommendations to the Secretary. I look forward to hearing from you.

Sincerely,

Charles E. Grassley
United States Senator

cc: Jeffrey S. Blair
Vice Chair
Subcommittee on Standards and Security, NCHVS

APR 28 2005

From: Martin, Ross
Sent: Thursday, February 24, 2005 6:11 PM
To: Maria A. Friedman D.B.A. (mfriedman@cms.hhs.gov)
Cc: 'ktrudel@cms.hhs.gov'; simon.cohn@kp.org; Jeff Blair (jeffblair@medrecinst.com); Stanley M. Huff, MD (email - coshuff@ihc.com); 'Harry.Reynolds@bcbsnc.com'; 'jwarren2@kumc.edu'; 'sns6@cdc.gov'; J. Michael Fitzmaurice, PhD (mfitzmau@ahrq.gov); David Brailer MD, PhD (david.brailer@hhs.gov); D. Clay Ackerly (dackerly@cms.hhs.gov); Carey, Chris; Glasser, Allison; Labkoff, Steve; Ho, Yin; Friede, Arnold I.; LaMarca, Lou; Wilson, Anne E; Lucas, Charles (Ny-Legal); Gleason, Brenda; Lukshis, Joe
Subject: Recommendations to CMS on 2006 MMA eRx Pilot Activities

CMS-0011-P

Maria –

Thank you for the opportunity, as presented by Karen Trudel at the last National Committee on Vital and Health Statistics (NCVHS) hearing on electronic prescribing (eRx) standards, to provide comments to CMS as you prepare the RFPs for the 2006 eRx pilots under the Medicare Modernization Act of 2003 (MMA). We are very interested in supporting these pilot efforts as we believe they will provide essential insights to CMS, patients, and the industry as a whole and will be instrumental in aiding CMS in the development of eRx standards that advance the stated goals of the MMA's eRx provisions – namely, to improve patient safety, improve the quality of care provided to patients, and increase efficiencies in the delivery of care.

Knowing that you are in the throes of preparing for the procurement process and are under tight deadlines, we have quickly assembled this set of comments that, we hope, will help you conduct informative pilots where adequate industry experience is lacking. The MMA eRx program will undoubtedly have a profound impact on the entire healthcare landscape. Therefore these pilots can do much more than simply provide insights on the initial set of standards CMS will require for eRx under MMA; they can also help the industry gain a greater understanding of the overall impact of eRx and highlight opportunities for future standards as we progress along this continuum of connectivity in healthcare.

As you may recall from Pfizer's testimony to NCVHS last year, we are basing our perspective on this subject on three core principles – *put patients first; support the clinical judgment of healthcare professionals without controlling them; and ensure the integrity of information used in clinical decision-making*. With these core principles and the primary objectives of the MMA's eRx provisions in mind, we request that CMS conduct pilots in 2006 that will target the following objectives:

- Provide a broad analysis of the entire eRx workflow – including the foundational standards for which adequate industry experience exists – to demonstrate the benefits, calculate total-cost-of-care benefits, identify potential obstacles to widespread adoption, and identify areas where appropriate incentives may be required to ensure adoption.
- Examine the use of RxNorm in capturing prescriber intent when used to bridge between systems using disparate drug knowledgebases.
- Examine the use of the RxFill message to improve patient compliance and outcomes and identify potential mechanisms for ensuring its broad adoption.
- Demonstrate the use of the NCPDP-HL7 mapping work to improve outcomes for patients who are discharged from the hospital setting with prescriptions that will be filled at a retail pharmacy.
- Examine the entire prior authorization process and demonstrate the use of existing and emerging standards from X12, HL7 and NCPDP to support electronic adjudication of prior authorization requests.

In the paragraphs that follow, we outline these objectives in greater detail.

Overall eRx Workflow

prescribed therapy. Clinicians could then provide counseling to patients about taking their medications as prescribed and avoid the pitfalls of assuming drug therapy failure and switching medications or increasing dosing unnecessarily. Inclusion and testing of such functionality in the pilots would directly address the MMA's stated objectives of providing prescribers with greater medication history data at the point of care. Given the wealth of data demonstrating the quality gains that achievable through improved medication adherence, the lessons learned in these pilots would also be instrumental in enhancing the quality of care.

Pfizer requests that CMS conduct a pilot investigating the impact of providing routine RxFill messages to Medicare patients – especially those on chronic meds whose long-term outcomes can be improved with increased adherence to prescribed therapies.

HL7 to NCPDP SCRIPT eRx Transactions

Pfizer has played a leading role in coordinating industry efforts to map HL7 and NCPDP SCRIPT electronic prescribing standards. The recent demonstration conducted in HL7's booth during the HIMSS conference was a clear success and generated significant interest among stakeholders that were not involved in the initial project. While we have been able to successfully demonstrate that the exchange of electronic prescription messages between HL7-based systems (i.e., hospitals and integrated delivery networks) and NCPDP SCRIPT-based systems (i.e., retail pharmacies) is feasible, these transactions have yet to be demonstrated in a "real world" setting. Among other benefits, the successful enablement of electronic prescribing between these systems will address a critical and well-recognized gap in advancing patient safety, namely, the patient care handoff that occurs when a patient is discharged from a hospital with prescriptions that are to be filled in the retail setting. It will also provide needed guidance for HL7-based institutions comply with the proposed rules.

The mapping efforts to date have focused on HL7 v2.x and NCPDP SCRIPT v5.1. There is concern among the mapping team that the work done to date will only go so far to assist in making the translation of these kinds of transactions more straightforward. The challenge can largely be attributed to the many customizations that are unique to each implementation of these standards. In HL7 implementations in particular, the use of "z-segments", which allow for implementation-specific messages that are not constrained by a common methodology, make it very challenging for anyone attempting to map their customized HL7-based systems to NCPDP SCRIPT using our current guidance documents as a reference.

Members of the mapping workgroup are hoping to complete our work on the 2.x mapping and move to mapping NCPDP SCRIPT to HL7 v3, which is much more constrained and therefore subject to significantly less variability between implementations. This mapping effort could create mapping guidance that will be much more universally applicable.

At this point, the mapping team needs a tangible goal to target in order to move this work forward at a more rapid pace. *Pfizer requests that CMS conduct a pilot to examine the exchange of eRx messages between HL7-based systems and NCPDP SCRIPT-based systems and include in this pilot a mechanism for publishing the "lessons learned" from the pilot, including more detailed guidance on mapping between the two messaging standards.*

Pilots on Prior Authorization (PA)

As you are well aware, NCVHS received a great deal of testimony on prior authorization and the burden it places upon prescribers who attempt to prescribe clinically appropriate medicines that require PA to their patients. Some recent surveys shed additional light on this issue:

- In a survey of conducted in the summer of 2004 by SureScripts and Physicians Interactive, a research division of Allscripts, 2888 physicians were asked about their attitudes on eRx. When asked to prioritize the potential benefits of eRx on their practices, **decreasing "the hassles associated with prior authorization" was the**

highest ranked opportunity – higher than improved access to prescription history (2), formulary information (8), decreasing calls between pharmacy and prescriber (3), easier renewal authorizations (4), or medication adherence tracking (5). *Source: SureScripts Fall 2004 Newsletter – www.surescripts.com*

- Point-of-Care Partners conducted a survey of 25 executives from large health plans at the behest of Pfizer in November of 2004 to better understand plans' attitudes about PA. Pfizer supported this research in response to testimony from the PBMs that there was little interest among payers to automate PA. We doubted this assertion as health plans, in contrast to drug cost carve-out PBMs, have a greater interest in ensuring that their beneficiaries receive appropriate therapy – even high-cost drugs – when they can serve to reduce the total cost of care (i.e., keep patients out of the hospital, emergency department and operating room). In the survey, **Ninety-six percent of the executives support automation of Prior Authorization at point of care** to reduce administrative costs and increase clinically appropriate prescribing. The most common barriers identified by these executives were the lack of physician office technology and the lack of standards. *Source: POCP. Research in submission*

Congress foresaw the importance of PA on the delivery of pharmaceutical care when it explicitly required inclusion of PA requirements in the scope of information that must be provided to prescribers who use eRx for Medicare Part D beneficiaries. In conducting pilot tests that will be the basis for the next round of eRx standards, we believe CMS has the unique opportunity to facilitate the integration of electronic PA adjudication processes into the eRx workflow. Not only would such a focus be responsive to congressional intent and advance the stated objectives of the statute – namely, higher-quality care and improved practice efficiency, but it would also serve to alleviate the burdens so clearly expressed in the survey results cited above.

During the January 2005 NCVHS Subcommittee hearing, Lynne Gilbertson of NCPDP provided testimony on the initial findings of the recently formed PA task group. The task group is seeking to develop a comprehensive overview of PA and determine where various standards could help to streamline this process. The task group has found that multiple standards from multiple Standards Development Organizations (SDOs) – including X12, NCPDP and HL7 – would be required to effectively adjudicate PA electronically. We have provided greater detail on these transaction standards at the end of this email.

There is a strong need to demonstrate a "soup to nuts" approach to PA adjudication that examines the entire PA flow and the interaction of all the messaging and formatting standards. *Pfizer requests that CMS conduct a pilot examining the entire prior authorization process and the standards that could be used to support this process.* Such a project would need to show several interactions:

- Payers using the clinical guidelines standard to author and structure PA requirements in such a way as to support the aggregation and distribution of PA requirements from multiple benefit plans in a consistent manner.
- eRx vendors uploading the structured PA requirements from multiple plans into an eRx system that can be presented to the clinician at the time of prescribing.
- Prescribers viewing and providing responses to the structured PA requirements during the prescribing process.
    - The structure of the PA requirements will facilitate the ability of the eRx tool to present only those questions that are relevant to the patient in question using branching logic (i.e., not asking the clinician to confirm menopausal status in a male patient).
- Prescribers submitting a complete set of PA requirement responses to a payer in an HL7 clinical document attached to an X12N 278 PA request.
- Payers sending a response to the prescriber's PA request using the X12N 278 standard – including all permutations of possible answers (approval with an accompanying code, rejection with reasons, etc.)

Industry already has adequate experience on the remaining portions of the PA process, including the delivery of the PA approval code from the prescriber to the pharmacy (using the NCPDP SCRIPT standard) and the adjudication of the claim (including transmission of the PA approval code) between the pharmacy and the payer (using the NCPDP Telecom standard). But these capabilities should be included in the pilot to show the entire workflow. The pilot should also examine the overall burden of the current process to prescribers and patients, the impact of the PA process on patient access to clinically appropriate medicines, efficiencies gained when using the proposed standards, implementation considerations, and gaps in the proposed methods for electronically enabling the PA process.

Follow Up

Pfizer has been actively encouraging other industry stakeholders to comment on the pilots by spreading the word about this opportunity to comment at last week's HIMSS conference and during recent NCPDP task group calls. While there has been strong interest in responding, the limited window of opportunity is preventing some from finalizing their comments in time. As a result of these constraints, for example, NCPDP has opted not to comment as an organization, but has encouraged individual companies to provide comments. While we cannot claim to have an official endorsement from these organizations, we believe that the recommendations we are outlining below echo the sentiments of many industry stakeholders and encourage CMS to seek additional comments.

We would welcome the opportunity to discuss these recommendations with you and your staff and provide more detail on any of the points made in this email. We have been very active in the standards work alongside many other industry stakeholders – especially around prior authorization and HL7-NCPDP mapping. The 2006 pilots conducted by CMS will undoubtedly set the stage for eRx – not just for Medicare, but for all of healthcare in the US and abroad. We look forward to helping make an appropriately designed electronic prescribing infrastructure a reality for our Medicare beneficiaries.

Regards,

Ross D. Martin, MD, MHA

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Additional Detail on the Standards Required for Electronic Adjudication of Prior Authorization

Please refer to Lynne Gilbertson's testimony to NCHVS from February 1st, 2005 for an overview of the progress of the NCPDP task group on prior authorization. The following information provides further detail on the standards required for fully electronic processing of PA requests. This set of standards represents one potential workflow strategy among several that could be employed to achieve this goal.

- *X12N 278 for the inquiry and response from prescriber to payer* – This HIPAA-designated standard was designed for procedure/pre-admission authorization and requires numerous workarounds to accommodate eRx. There is little industry experience for using this standard for medication PA. X12, with active participation from NCPDP members, has Work by an NCPDP task group (with participation of members of HL7 and X12) has now begun developing guidance on how the 278 standard could be employed

for this purpose. X12 275 may also play a role in delivering the HL7 claims attachment to the PDP.

- *HL7 Claims Attachment Standard for attaching clinical justification of the PA request from prescriber to payer* – Industry is anticipating HHS' release of its rule on health claims attachments in May of this year. Within the context of PA, this standard would be used as the container for the prescriber's response to the PA requirements as articulated by the payer. The standard is modeled after HL7's v3-based Clinical Document Architecture standard. As stated in testimony by representatives of X12 at the NCVHS hearings, there is little industry experience in employing the claims for this purpose.
- *HL7 clinical guidelines standards (including GELLO)* – One of the most important aspects of streamlining the PA process in terms of ensuring interoperability and greater process efficiency is creating a common structure for the PA requirements. Standardization of the PA requirements structure will help ensure interoperability while still leaving the individual criteria contained within the PA requirements up to the payer. In other words, while an individual PDP may require that a patient be over 55 years old to qualify for a particular medicine, in order for interoperability to be achieved, the PDP will need to ask the question in the same manner as every other PDP ("Pt_age >= 55", for example).
    - HL7's Clinical Guidelines SIG has done a great deal of work on creating the type of standards required for this kind of capability. The structure required for adjudicating PA requirements is actually much simpler than other types of guidelines because these are static, point-in-time requirements that are either true or false at the time of prescribing. There is no need to track a patient's progress through a clinical guideline over time before arriving at another decision point. We presented this need to the Clinical Guidelines SIG at the last HL7 workgroup meeting in January 2005. Several members of the SIG expressed a strong interest in working with us to show how GELLO, a query and expression language being developed through the SIG, and other clinical guidelines standards could be used to meet this need. They are preparing demonstrations of this capability for the upcoming NCPDP workgroup meeting in March 2005. With active participation of the SIG, such a capability could be ready to test in time for the 2006 pilots. These standards are still in the balloting stage and would need to complete the balloting process to become an ANSI-accredited standard.
- *NCPDP SCRIPT Standard*
    - NCPDP SCRIPT already has fields in place for transmitting a PA approval code from the prescriber to the pharmacy after the prescriber has received the PA code from the PDP.
    - NCPDP SCRIPT also has fields in place for transmitting a message from the pharmacy to the prescriber indicating that PA code, in the event that a prescriber sends a prescription requiring PA without a PA approval code, is required.
- *NCPDP Telecom Standard*
    - NCPDP Telecom Standard already has fields in place for transmitting a PA approval code from the pharmacy to the payer.
    - NCPDP Telecom Standard already has fields in place for indicating that a claim is being rejected because the prescribed drug requires a PA approval code.
    - These functions of the NCPDP Telecom Standard are in widespread use and do not, of themselves, require testing.

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APR 29 2005

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April 5, 2005

BY ELECTRONIC SUBMISSION

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P,
Box 8014
Baltimore, MD 21244-8014

Re: CMS-0011-P (Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256)

Dear Dr. McClellan:

Wyeth Pharmaceuticals welcomes the opportunity to comment on the proposed rule by the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* on February 4, 2005 ("proposed rule") on electronic prescribing standards under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and healthcare products companies with leading products in the areas of women's healthcare, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology, and vaccines.

Section 1860D-4(e) of the MMA establishes a voluntary electronic prescribing (e-prescribing) program and requires the development of national e-prescribing standards. Beginning in 2009, the final e-prescribing standards will be mandatory for Medicare Part D providers who adopt e-prescribing in 2009. Based on recommendations from the National Committee on Vital and Health Statistics (NCVHS), CMS suggests the adoption of foundation standards as the basis for a more complete set of e-prescribing standards in the future.

Wyeth commends CMS for its efforts in the proposed e-prescribing rule to improve the quality of care for Medicare beneficiaries. Wyeth believes it is

critical for an e-prescribing system to improve the quality of care and to strengthen the physician-patient relationship. In this spirit, we respectfully offer comments and recommendations to CMS in the following areas:

1) The impact of financial incentives for e-prescribing adoption on both prescribers and Medicare Part D sponsors,
2) The impact of e-prescribing adoption on health outcomes and quality of care,
3) The use of e-prescribing to facilitate enabling automatic prior authorization, and
4) Prescribing information and its presentation format through e-prescribing.

Recommendations

1) **CMS should not allow Part D sponsors that offer financial incentives to physicians for adopting e-prescribing to inappropriately influence physician prescribing behavior or restrict choice of medicines.**

The proposed rule allows Medicare Advantage plans to provide financial incentives to physicians for adopting e-prescribing under the Medicare Part D program in accordance with the established standards. These payments are intended to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. Accordingly, CMS will publish a proposed rule to create an exception under the Stark law for incentives related to e-prescribing. Also, the Office of Inspector General in the Department of Health and Human Services (HHS) will establish a safe harbor under the Anti-Kickback Statute.

As CMS indicated in the propose rule, "health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance.[1]" While we understand the goal of health plans to achieve positive returns on the costs associated with e-prescribing, Wyeth believes that health plans should not be allowed to use financial incentives to inappropriately influence physician's prescribing habits. The e-prescribing system should protect physician's prescribing autonomy and support physicians

[1] Fed. Reg. Vol 70, No. 23, at 6269

choosing treatment therapies primarily based on clinical judgment rather than cost concerns or financial incentives.

- In the final rule, CMS should ensure that the use of financial incentives do not inappropriately influence physician prescribing behavior or restrict provider choice and decision-making. For example, physicians should not be penalized or discouraged from prescribing clinically appropriate but off-formulary drugs if they deem these drugs to be the most appropriate treatment for their patients.

- CMS should also prohibit plans from incentivizing physicians solely on the basis of their performance in containing costs. For example, plans should not be allowed to set targets for generic prescribing or preferred tier prescribing and reward physicians on the basis of their performance in meeting those targets.

2) CMS should examine the impact of e-prescribing adoption on health outcomes and overall patient quality of care.

While e-prescribing is gaining acceptance by health care providers, CMS estimates that only 5 to 18 percent of physicians currently use e-prescribing.[2] The adoption rate is particularly low among solo practitioners, those in rural areas, and certain medical specialties.[3] Given many uncertainties about e-prescribing and possible unintended consequences, we recommend CMS give special considerations to the following areas in developing final e-prescribing standards and making implementation decisions.

- Wyeth believes that the primary drivers for e-prescribing adoption should be the improvement of patient safety and quality of care. However, plans have focused heavily on using e-prescribing to improve formulary compliance, increase generic utilization, and reduce pharmaceutical and administrative costs. We recommend that CMS conduct analyses of e-prescribing's impact on formulary compliance, generic utilization and their impact on patient care, health outcomes and overall quality of care.

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[2] Fed. Reg. Vol. 70, No. 23, at 6260
[3] 69 Fed. Reg. at 46672

- In its analyses, CMS should recognize the potential unintended consequences of e-prescribing. For example, if plans are authorized to compensate prescribers who use e-prescribing on the basis of their performance on formulary compliance and/or whether meeting cost containment targets, patient access to medicines may be inappropriately limited by under-prescribing. Under-use of clinically appropriate treatments may not only have a negative impact on health outcomes but also increase the total healthcare costs. Studies have found that appropriate use of pharmaceuticals produces savings from reduced use of medical services as well as from improvements in patients' health, quality of life, longevity, and economic productivity.[4] A study conducted by Dr. Frank R. Lichtenberg concludes that each dollar increase in pharmaceutical spending yields a reduction in hospital expenses of $3.65.[5]

- CMS' analyses should also examine how the use of e-prescribing could maximize potential savings to the Medicare program through improvements in patient safety, quality of care, and health outcomes. These savings could be realized through:
  - reduction in medication errors and adverse events,
  - reduction in total healthcare costs due to appropriate drug utilization (e.g., from adherence to recognized clinical treatment guidelines),
  - improvements in patient medication compliance and persistency,
  - and more efficient communication and prescription transactions among prescribers, dispensers, and plan sponsors, through the use of tools such as automated prior authorization.

3) E-prescribing system should be designed to allow for automated prior authorization at the point of care.

Prior authorization (PA) is a requirement placed on certain drugs to encourage appropriate clinical usage and contain drug expenditures, especially for higher cost medicines (e.g., biologics) or therapeutic categories. NCVHS estimates that 2 percent of prescriptions are subject to PA requirements, and that there is a higher rate in the Medicaid program.[6] Prior authorization is now commonly used

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[4] Meyer, J. *Assessing the Impact of Pharmaceutical Innovation*, 2002

[5] Lichtenberg, F. *Pharmaceutical Innovation, Mortality Reduction, and Economic Growth*, 1999.

[6] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm

in prescription drug benefit programs administered by private health plans and Medicaid. According to the Medicare Payment Advisory Commission (MedPAC), it may be used even more frequently in the Medicare Part D program.[7]

The request for a prior authorization for a drug from the prescriber to the payer/Pharmacy Benefits Manager (PBM) is now conducted manually.[8] The manual processes, which may involve coverage denials at the pharmacy counter, phone calls among prescribers, dispensers and plans, and waiting periods for patients—are an administrative burden for patients, pharmacies and prescribers. As a result, medical staff time may be diverted from patient care and education to handling the voluminous paperwork and increased telephone calls from patients.[9] In addition, a manual PA process may require plans to hire extra personnel to handle prior authorization calls.

While PA may provide short-term savings to plans, it may have a negative impact on patient care. Because manual prior authorizations take time to be processed, they can result in unnecessary delays in patient treatment and higher administrative costs. A recent MaineCare study on prior authorization reports that some patients experience dangerous side effects or even a worsening of their medical conditions as they go through the PA process before they are allowed to take an effective medication that is subject to PA.[10] According to the report, consumers find the manual process confusing and frustrating. As a result, instead of trying to navigate the PA process, some patients will simply not get the prescribed medication while others will have to pay the full cost of a drug when told their plans will not cover it at the pharmacy counter.

The MaineCare report concludes that aspects of the current PA implementation have adverse consequences directly affecting patient care and medical practices of providers. These consequences may, in turn, result in hidden and unintended

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[7] MedPAC public meeting, March 10, 2005

[8] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm

[9] *The MaineCare Advisory Committee's Prior Authorization Subcommittee Report and Recommendations on Prior Authorization for Prescription Drugs in the MaineCare and Drugs for the Elderly Programs*, January 19, 2005.

[10] Ibid.

costs to the healthcare system.[11] To improve patient care by avoiding unnecessary delays and improving efficiency, Wyeth believes that the e-prescribing system should be designed to help facilitate and fully automate the PA process. In an automated PA system, physicians would be notified at the point of prescribing that a medicine is subject to PA and empowered to enter relevant information that would, if appropriate, provide immediate patient access to the drug.

For example, etanercept is a tumor necrosis factor (TNF) inhibitor indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Many plans impose prior authorization requirements on etanercept before RA patients are provided access to the treatment. Typically, plans request two types of data to process a prior authorization for etanercept: patient diagnosis and previous failed drug therapy(ies). Since the e-prescribing system provides real-time information regarding a patient's eligibility and benefits, including a requirement for PA as well as patient's medication history, physicians should be able to submit a PA request for etanercept through e-prescribing and be informed whether the application is approved at the point of care.

A fully automated PA process will improve patient quality of care, ensure prescribing efficiency and reduce prescribing costs. We believe that the value of an e-prescribing system would be significantly diminished if prescribers must manually submit PA requests. We urge CMS to consider NCVHS' recommendation that HHS should evaluate the economic and quality of care impacts of automating prior authorization communications between dispensers and prescribers and between payers and prescribers in its 2006 pilot tests. [12]

4) **Standards for the e-prescribing user interface and presentation of drug lists and formularies should ensure that appropriate, accurate and up-to-date information is presented in a comprehensive and neutral format.**

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[11] Ibid.

[12] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm

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The use of e-prescribing should not inappropriately steer or influence a physician's clinical decision-making or prescribing practices. The content and completeness of the information provided by the system, along with the structure, format, and organization of the formulary and user interface within the e-prescribing technology will undoubtedly impact and influence a provider's prescribing behavior. For example, if the initial e-prescribing interface only provides a list of generic or preferred innovator medicines covered by the plan and requires physicians to scroll through additional pages to access and prescribe alternative therapies, a physician's prescribing choices may be negatively impacted. Patients' access to needed medicines may also be effectively limited. We believe that CMS should be cognizant of these issues and develop standards that will guarantee comprehensiveness and neutrality in the e-prescribing process.

CMS should ensure that future rulemaking on standards for the e-prescribing user interface and presentation of drug lists and formularies address the following issues:

- Physicians should have easy access to the comprehensive list of available drugs and the information should be presented in a single, neutral, and comprehensive format (e.g., alphabetically).

- The user interface should not create barriers to prescribe non-preferred or off-formulary drugs. It also should not limit the ability of physician to prescribe drugs for clinically appropriate off-label uses.

- E-prescribing should not interrupt a physician's workflow—e.g., wading through multiple pages to view drug choices, or pop-up windows with information about formulary or prior authorization.

- The system should provide up-to-date, accurate, and comprehensive information to assist physician communicating with the patient at the point of care, such as information about appropriate drug utilization.

- The system should also provide information needed for timely access by beneficiaries to clinically appropriate treatment, such as accurate and easy-to-understand information about exceptions and appeals.

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- The system should be updated on a timely and frequent basis so that real-time information will be presented to ensure patient access to new drugs and drugs with new indications.

Conclusion

Wyeth believes that e-prescribing holds the potential to be used as a tool to reduce prescribing errors, improve patient safety, health outcomes and quality of care, and improve prescribing efficiency. To achieve these goals, e-prescribing should not be used to limit physician prescribing choices, or patient access to clinically appropriate medications. E-prescribing also should not inappropriately influence physicians' decision-making, interfere with physicians' workflow or impede their ability to make appropriate clinical and pharmacological choices.

We appreciate this opportunity to provide CMS with comments and recommendations on e-prescribing standards and the e-prescribing program under the Medicare Part D program. We look forward to working with CMS in future e-prescribing rulemaking and the implementation of the e-prescribing program. If there are any questions about Wyeth comments, please do not hesitate to contact me.

Sincerely,

Lucinda E. Long

Lucinda E. Long